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Research Governance Standard Operating Procedures (Including ethics review processes)

February 2022

Research Governance Standard Operating Procedures
(Including ethics review processes)

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2.1	2 February 2022	Numerous updates reflecting changes to legislation or processes

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- When using this document ensure that the version you are using is the most up-to-date either by checking on the Research Governance webpages for any new versions or by contacting the author 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 uncontrolled
- Out of date documents must not be relied upon

Contents

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Science and Technology Research Ethics Committee (SCITEC	crecscitec@sussex.ac.uk	
Brighton and Sussex Medical School Research Governance Committee (RGEC)	rgec@bsms.ac.uk	
Animal Welfare and Ethical Review Body (AWERB)	awerb@sussex.ac.uk	
Insurance Manager	insurance@sussex.ac.uk	01273 873934
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1. INTRODUCTION TO THE UNIVERSITY'S RESEARCH GOVERNANCE FRAMEWORK AND ETHICS REVIEW PROCESSES

The University of Sussex is committed to promoting and upholding the highest quality academic and ethical standards in all its activities. The University's approach has been to develop research governance and ethics policies and procedures which recognise the importance of addressing ethical matters, while supporting the achievement of its collective research objectives.

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*[1].

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. To find out more about the University's approach to Research integrity visit the Research Standards webpage page.

To this end, robust research governance procedures and policies underpin all research at the University. The University's Research Governance Framework (see figure 1) ensures that discipline-appropriate review occurs in a timely manner.

Ethical review at the University also takes into account the level of risk associated with any project in order to ensure that the review process is proportionate.

- Low-Risk Undergraduate (UG) and Postgraduate Taught (PGT) student projects are reviewed at School level by a Supervisor and a School Research Ethics Officer;

- All Staff and Postgraduate Research (PGR) student projects are reviewed by a Cross-Schools Research Ethics Committee (C-REC). Higher risk UG and PGT student projects also go to a C-REC for review.

- All research undertaken by members of Brighton and Sussex Medical School (BSMS) or that is health or medical related (from across the University) undergoes a standard level of review by the BSMS Research Governance and Ethics Committee (RGEC).

- The Animal Welfare and Ethical Review Body (AWERB), with a specific composition, considers all research which involves animals that is both specifically covered by the Animals Special Procedures Act (1986) (ASPA) and that which is not covered by the Act. In all cases, the AWERB will need to satisfy itself that such projects are ethically acceptable to the University, that all relevant regulations are complied with, and that all potential harms to animals, however mild, are reduced to a minimum. Applications to the AWERB are **not** made through Sussex Direct but instead via the Secretary to the AWERB [2].
- Studies that have *both* human and animal ethical implications will be considered on a case by case basis and may involve co-opting members across review bodies to give

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[1] Both documents can be found at http://www.sussex.ac.uk/staff/research/rqi/policy/research-policy
[2] Please see http://www.sussex.ac.uk/staff/research/governance/erp_overview/animals/awerb for contact details.

advice and expertise as appropriate[3].

- Studies that involve NHS patients, their data or tissue, NHS staff or facilities require a process known as Sponsorship (see section 8 below).

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[4]. Schools report to the Cross School Research Ethics Committee (C-REC) that normally covers their School's ethics review. All Committees with ethics review responsibilities report to the Research Ethics and Integrity Committee (REIC). REIC is responsible for broader policy decisions relating to research governance and ethics review.

REIC also monitors and audits decisions at School-level and by C-RECs to ensure that ethics review is following the University's research governance policies and procedures. The REIC is responsible for regularly reviewing policies relating to the ethics and integrity of research to ensure that they are comprehensive, accessible, relevant and up-to-date.

(NOTE: Formal Terms of Reference for committees with ethics review responsibilities are appended to Annex A. Role descriptions for key ethics review personnel are appended to Annex B.)

See below for a diagram setting out the University's Research Governance Framework:

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[3] The Research Governance Officer (rgoffice@sussex.ac.uk) can give advice in such instances.
[4] https://direct.sussex.ac.uk/page.php?realm=research&page=ethical_review_list

Sussex Research Governance Committees Framework

SENATE

RESEARCH INTEGRITY AND ETHICS COMMITTEE

RESEARCH AND KNOWLEDGE EXCHANGE COMMITTEE

SOCIAL SCIENCES AND ARTS CROSS SCHOOLS RESEARCH ETHICS COMMITTEE
(SSARTS)

SCIENCE AND TECHNOLOGY CROSS SCHOOLS RESEARCH ETHICS COMMITTEE
(SCITEC)

BRIGHTON AND SUSSEX MEDICAL SCHOOL RESEARCH ETHICS AND GOVERNANCE COMMITTEE
(BSMS RGEC)

RESEARCH GOVERNANCE AND QUALITY ASSURANCE COMMITTEE

School research ethics officers
(SREOs)

School research ethics officers
(SREOs)

School research ethics officers
(SREOs)

SPONSORSHIP SUB-COMMITTEE
(NHS RESEARCH & CLINICAL TRIALS (CTIMPS)

AWERB
(ANIMAL WELFARE AND ETHICAL REVIEW BODY)

HUMAN TISSUE ACT LICENCE CO-ORDINATION GROUP

Research Ethics, Integrity and Governance Team, Research and Enterprise Services

SSARTS C-REC (Business School, Education and Social Work, Global Studies, Law, Politics and Sociology, Media, Arts and Humanities)

Tim Parkinson — Tim.Parkinson@sussex.ac.uk

SCITEC C-REC (Engineering & Informatics, Life Sciences, Mathematical & Physical Sciences, Psychology)

Lauren Shukru — l.shukru@sussex.ac.uk

BSMS RGEC (Brighton and Sussex Medical School)

Caroline Brooks— c.e.brooks@bsms.ac.uk

AWERB

Kate Gannon—kg340@sussex.ac.uk

Research Governance Officer (Sponsorship, Human Tissue research, allegations of research misconduct)

Antony Walsh— antony.walsh@sussex.ac.uk

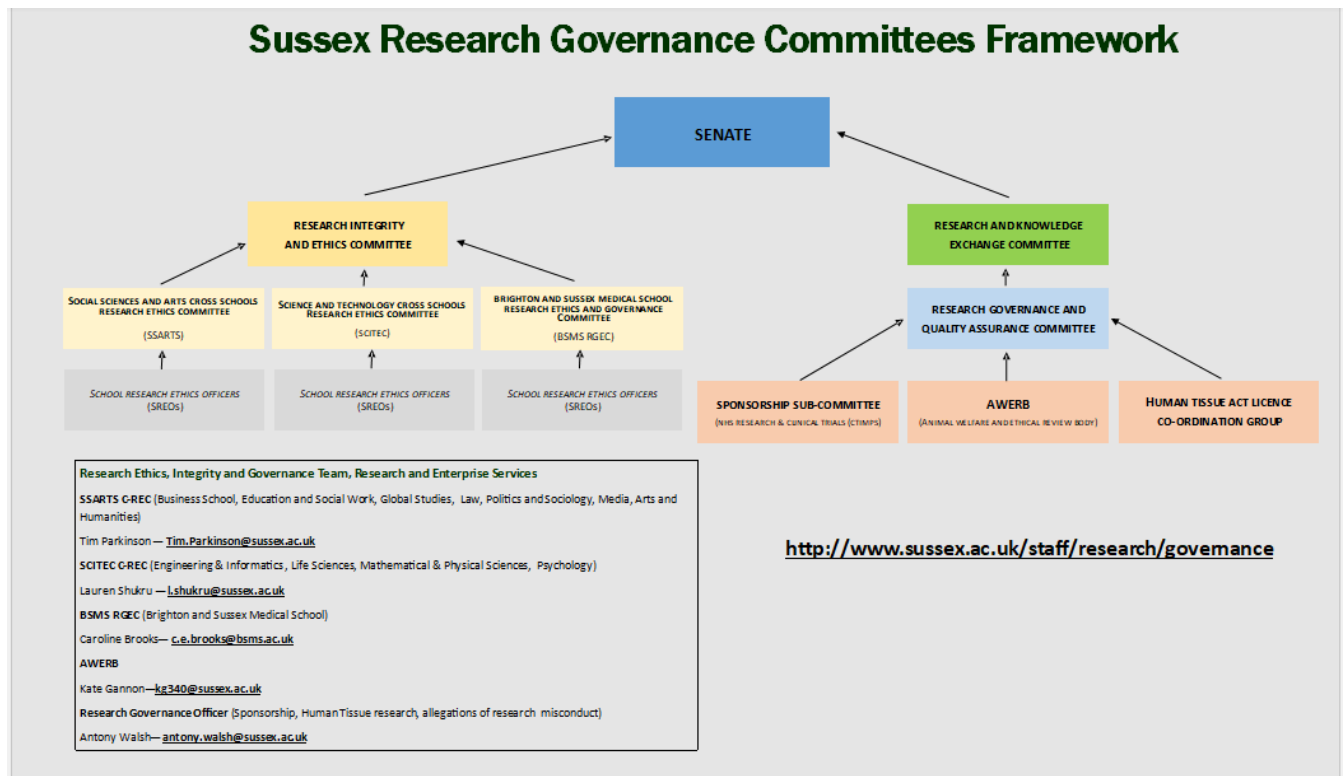http://www.sussex.ac.uk/staff/research/governance

Figure 1: University Research Governance Framework

2. ASSESSING WHETHER ETHICS REVIEW IS REQUIRED

The following 5-question self-assessment checklist can help to guide all researchers in determining whether their proposed research requires an ethics review.

Does my research require ethics review?

A 5-question self-assessment checklist

1. **a.** Will the research project involve human participants, with or without their knowledge or consent at the time? (This includes yourself if you are the main
subject of the research.) YES / NO

   b. Will the research project involve animals? YES / NO

2. Is the research project likely to expose any person, whether or not a participant, to physical or psychological harm? YES / NO

3. Will you have access to personal information that allows you to identify individuals or to confidential corporate or company information? YES / NO

4. Does the research project present a significant risk to the environment or society? YES / NO

5. Are there any ethical issues raised by this research project that require further ethics review? YES / NO

If you answered 'yes' to any of the above questions, then some form of ethics review will be necessary. NOTE: RESEARCH MUST NOT COMMENCE BEFORE ETHICS APPROVAL HAS BEEN GRANTED.

If you are uncertain please discuss with your Supervisor (if you are a student) or your School Research Ethics Officer (SREO), or contact a member of the Research Ethics, Integrity and Governance team: **rgoffice@sussex.ac.uk**

If the researcher answers **NO** to **ALL** of the questions, then no formal ethics review is necessary. If they answer **YES or MAYBE** to **ANY** of the questions, then they will be required to apply for some form of University or national level ethics review.

This checklist should be embedded in School processes and will be more important in those Schools where ethics review is not a standard feature of research (since staff and students in those Schools which routinely conduct research with human participants will be aware that ethics review is required). The checklist will be particularly important for projects where the researcher is not sure whether or not ethics review is needed. The goal of the five questions is to flag up any areas of potential risk to participants, the researcher, or the environment. *Researchers must not start their research until they have the appropriate ethics approval and permissions to commence their research.*

The following flow-chart provides an overview of ethics review at the University :

Complete Section A (Checklist) of the On-line Ethics Review Application Form

↓

IS THE PROJECT LOW RISK OR HIGH RISK?

LOW RISK UG / PGT STUDENTS	HIGH RISK UG / PGT STUDENTS	LOW RISK STAFF / PGR STUDENTS	HIGH RISK STAFF / PGR STUDENTS
SCHOOL REVIEW PROCESS ➢ Complete **Section B** of on-line Ethics Review Application Form ➢ Submit to 1) Supervisor and 2) School Research Ethics Officer (SREO) for review	CROSS-SCHOOLS RESEARCH ETHICS COMMITTEE (CREC) ➢ Complete **Section C** of on-line Ethics Review Application Form ➢ Submit to 1) Supervisor and 2) School Research Ethics Officer (SREO) for review	CROSS-SCHOOLS RESEARCH ETHICS COMMITTEE (CREC) ➢ Complete **Section B** of on-line Ethics Review Application Form ➢ **Staff:** Submit to CREC for review ➢ **PGR students:** Submit to 1) Supervisor and 2) CREC for review	CROSS-SCHOOLS RESEARCH ETHICS COMMITTEE (CREC) ➢ Complete **Section C** of on-line Ethics Review Application Form ➢ **Staff:** Submit to CREC for review ➢ **PGR students:** Submit to 1) Supervisor and 2) CREC for review
Review by SREO	Review by CREC: minimum number of reviewers = to Committee quorum	Review by CREC: minimum of one CREC reviewer	Review by CREC: minimum number of reviewers = to Committee quorum

3. OVERVIEW OF THE ETHICS REVIEW PROCESS AND SPONSORSHIP[5] REQUEST PROCESS

All staff and students whose research projects have been identified as requiring formal ethics review must apply for and receive some form of ethics approval *before* their research may commence. This also includes requirements for external review and approval where they exist.

Research projects that fall under the UK Framework for Health and Social Care Research [6], typically studies that involve NHS patients or service users, will need to be considered for formal University sponsorship.

The Health Research Authority considers a sponsor to be 'The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.'[7]

Sponsored studies are subject to a formal request and approval process following thorough risk assessment if the University is to grant sponsorship prior to the applicant seeking approval from a national ethics review body, for example NHS Research Ethics committees via the Health Research Authority (HRA) for research undertaken within the NHS.

The University requires that all new applications for sponsorship are reviewed and assessed by the **Pre-Sponsorship Review Panel (PSRP)**[8] before recommendation to the Sponsorship Sub-Committee that has oversight of all sponsored research.

Further detail on Sponsorship is provided in section 8 below.

It is a legal requirement for all Clinical Trials of an Investigational Medicinal Product (CTIMP)[9] to be sponsored. The term CTIMP applies to medicinal trials falling within the scope of the Medicines for Human Use (Clinical Trials) Regulations 2004. Research into medical devices comes under the Medical Devices Regulations (2002). Researchers who are in any doubt should take advice at the earliest opportunity[10].

In the case of externally funded research proposals, applications for ethics approval will normally be made once external funding has been approved, rather than at the point of application. However, as a matter of good practice, all bids for external funding should be subject to internal peer review prior to submission; this should include consideration of ethics and an understanding of their implications.

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[5] For more information about the Sponsorship process please see section 8 below.
[6] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/n . Individual frameworks also exist for Scotland, Wales and Northern Ireland - http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/
[7] http://www.hra.nhs.uk/resources/before-you-apply/roles-and-responsibilties/sponsor/
[8] https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx
[9] http://www.legislation.gov.uk/uksi/2004/1031/contents/made
[10] http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/study-types/

Ethical Review Application

Related Links ▼

Create Ethical Review Application			Cancel	Save	Help

Project Title *

Phone No.

Applicant Status   Staff

Project Start Date *   dd-mon-yyyy

Project End Date *   dd-mon-yyyy

External Funding in place ☐

External Collaborators ☐

Name of Funder

Project Description:
The project description should be a clear, easy to read summary that is as jargon free as possible. It provides an overview of the whole of your research study that readers can understand the first time they read it. Please see INVOLVE (http://www.invo.org.uk/) for further guidance on how to achieve this. *

3.1 The Online Ethics Review System

All staff and students applying for ethics review (*except* NHS, BSMS & CISC and all projects that are considered by the BSMS RGEC[11]) should complete the checklist in Section A of the University's online ethics review application form accessible within **Sussex Direct**[12].

The Section A checklist determines whether the project is low risk or higher risk.

» Checklist
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)?
A2. 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.
A3. 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).
A4. 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?
A5. Will the study involve discussion of sensitive topics (e.g. sexual activity, drug use, ethnicity, political behaviour, potentially illegal activities)?
A6. 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?
A7. Will your project involve working with any substances and / or equipment which may be considered hazardous?
A8. 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
A9. Will financial inducements (other than reasonable expenses, compensation for time or a lottery / draw ticket) be offered to participants?
» Risk Assessment
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:

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[11] All applicants for ethics review for NHS, BSMS & CISC (MRI scanning) projects undertake a 'standard' level of review when considered by the BSMS RGEC
https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx
[12] https://direct.sussex.ac.uk/page.php?realm=research&page=ethical_review_list

• Low Risk Projects: If the researcher is able to answer '**No' to all nine statements** in the Section A checklist of the University's online ethics review application form, then the project is assumed to be low risk. The researcher will then be presented with SECTION B of the application form for completion. Once the application form is completed, it should be submitted along with supporting documents for review: UG and PGT students apply through their School-level ethics review process (see Section 4.1), and Staff and PGR students apply to a C-REC for review (see Section 4.2).

• Higher Risk Projects: Those projects where the researcher has been *unable* to answer 'No' to all nine statements in Section A are regarded as higher risk projects. In these cases. The researcher will then be presented with SECTION C of the application form for completion. Once the application form is completed, it should be submitted along with supporting documents for review by a C-REC (see Section 5).

• Exceptional Cases for Low Risk Review : (Q.10 Risk Assessment, SECTION A) provides a section where a researcher can make an exceptional case for their project to be considered as low risk review, **even if they have been unable to answer 'no' to all nine statements** in SECTION A. The relevant C-REC Chair or School Research Ethics Officer (SREO) will make a judgement in this instance.

4. APPLICATION PROCEDURES FOR LOW RISK PROJECTS (SSARTS and SCITEC C-REC research governance only) [13]

4.1 Undergraduate (UG) and Postgraduate Taught (PGT) students

The following sets out the University's standard School-level ethics review process for low risk UG and PGT student projects.

> *Ethics Review Process – Low Risk UG & PGT Student Projects*
> - The University's normal requirement for ethics review of **low risk** Undergraduate (UG) and Postgraduate-taught (PGT) student projects, is that review be carried out at School-level.
>
> - As part of the process of completing the application form, UG and PGT students should read at least one code of conduct from a professional association relevant to the proposed research project or failing that the University's *Code of Practice for Research*[14].
>
> - UG and PGT students should complete SECTION A of the University's online ethics review application form. If they can answer 'no' to all the statements in the CHECKLIST in Section A, then the project is considered low risk. The student will then be presented with SECTION B of the application form for completion.
>
> - The student will submit their form to their supervisor, via the University's online ethics review application system. The Supervisor will review the application and once satisfied can then authorise the application, at which point it will pass it on to a second reviewer – the **School Research Ethics Officer** (**SREO**) (nominated by Head of School)[1]. The SREO will review the project and can grant approval, if they agree that the project is low risk, and that all ethical aspects to the project have been dealt with appropriately. If the Supervisor or SREO has concerns about the project the application should be returned to the student for revision and/or, if the Supervisor or SREO considers that it should be classified as higher risk, the project should be returned to the student for application to the C-REC for review.

Schools will establish their own administrative procedures to support this process, and make public these procedures within the School. The following guidelines should be considered:

1. The expected time for the project to be reviewed and approved by the supervisor and the SREO.

2. The procedure for checking amendments to the project proposal.

3. In those Schools where second review is carried out through SREO review, this process will need to be developed to ensure the appropriate number and range of projects are being moderated by the SREO (as outlined above).

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[13] Separate arrangements exist for research undertaken within the Brighton and Sussex Medical School and for research that has a health or social care dimension.
[14] http://www.sussex.ac.uk/staff/research/rqi/policy/research-policy

4.2 Staff and Postgraduate Research (PGR) students

Ethics Review Process – Low Risk Staff and Postgraduate Research (PGR) Student Projects

- Staff and PGR students should complete SECTION A of the University's online ethics review application form. If they can answer 'no' to all the statements in the CHECKLIST in Section A, then the project is considered low risk. The researcher will then be presented with SECTION B of the application form for completion.

- Once the application form is completed, it should be submitted along with supporting documents for review.

  - PGR Students submit their form and documents to their research Supervisor for authorisation. The Supervisor will then submit to the C-REC when they are satisfied that all the appropriate ethical issues in the research have been addressed.

  - Staff submit their form and documents directly to the C-REC for review.

- The project will be reviewed by a minimum of one C-REC members appointed by the Chair.[2]

5. APPLICATION PROCEDURES FOR HIGHER RISK PROJECTS

All Staff, PGR students, UG and PGT students proposing higher risk projects, must apply to a C-REC for ethics review. Projects are deemed to be higher risk and / or in need of full C-REC review if any of the following apply:

- The researcher was unable to answer 'no' to all nine statements in the SECTION A checklist of the University's online Application Form for ethics review;

- The researcher has specific concerns or has identified risks that require consideration within the more detailed high risk application form and require review by the C-REC;

- The supervisor of a student project has determined that it is not low risk;

- The SREO who has reviewed a student project has determined that it is not low risk and therefore requires further scrutiny;

- The project is externally-funded and a requirement of funding is full ethics review by a committee which includes lay membership.

5.1 C-REC full review process – for all Higher Risk projects

- All UG and PGT Students, and Staff and PGR students proposing higher risk projects, must apply for ethics review to a C-REC by completing SECTION C of the University's online ethics review application form. Applications will normally be made to the C-REC that covers the School in which the Principal Investigator (PI) is based. However, in some cases, the topic or context of the research may merit

review of the application by an alternative C-REC. Only one C-REC will consider each application.

- All students are expected to complete their application form in close discussion with their supervisor, and their supervisor must approve the application to confirm that this process has been followed. The responsibility for ensuring that research governance issues are properly considered in the application lies with the first-named supervisor or other staff member with responsibility for supervising the student's work.

- Once the application form is completed, it should be submitted along with supporting documents for review.

    - PGR students (and UG / PGT student high risk projects) submit their form and documents to their supervisor for authorisation. The supervisor will then submit to the C-REC when they are satisfied that all the appropriate ethical issues in the research have been addressed.

    - Staff submit their form and documents directly to the C-REC for high-risk review.

- Once an application form has been submitted, it will be circulated. The time required for the issuing of a decision will depend on the complexity of the specific case, the workload of the committee, and current projects under review.

6. C-REC REVIEW PROCEDURES – LOW, HIGHER AND STANDARD RISK REVIEW

- Members of the C-REC or RGEC must inform the Chair, at the start of a review or meeting, if they have a personal or financial interest in any research project or project funder. The Chair will decide whether the interest disqualifies the member from the discussion. Members of a C-REC or RGEC must withdraw from consideration of any submission in which they are researchers, supervisors or consultants.

- By invitation of the Chair, independent experts or others may take part in the discussion of a project to provide advice and assistance, subject to an undertaking of confidentiality.

- The Chair must appoint a deputy to cover periods of absence, absence at the University Research Ethics and Integrity Committee, or any conflicts of interest.

- Members of C-RECs or RGEC are asked to serve for a period of three years, renewable for further terms (which may be served with another C-REC).

- Decisions on high risk applications will only be made either at meetings or online discussion, where a quorum is present (half the committee, or minimum of three committee members (including the Chair), whichever of these is the greater), or where a quorum of members have submitted their opinions.

- The C-REC or the RGEC will aim, wherever possible, to reach a first decision within one month of receiving an application.

- Longer consideration may be necessary where potential hazards to the participants are

identified and the committee feels it may require expert advice. C-RECs undertake to give applicants an update regarding their proposal within a month, if a final decision has not already been made.

- Members will be asked to provide comments and their recommendations for whether or not an application should be approved. If there is no consensus, then decision can be made by majority vote. However, the Chair always has the authority to make the final decision based on their judgement as to which recommendations are the most appropriate. If a case is extremely complex and/or contentious, external expertise may be called upon to help resolve what, if any, modifications need to be made to the proposal.

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

    (i) **approve** the application as it stands or conditionally approve the application subject to minor corrections being made; or
    (ii) **require re-submission** of the application with amendments and / or request missing supporting documents; or
    (iii) **reject the application**.

- In the case of (ii) clear suggestions as to what revisions or amendments are required will be specified to the applicant.

- If an application is rejected, the researcher will be provided with clearly stated written reasons for this decision.

- Research should normally commence within 12 months of the date on which a favourable ethical opinion is given by a C-REC or SREO (as recorded in the Certificate of Approval). If not, the researcher has to re-apply after the expiry of that period. Generally, a study is deemed to have commenced when participants have been recruited or any of the empirical procedures in the research proposal are initiated.

- Notwithstanding a C-REC or SREO approval, the researcher will remain responsible for observing good practice and generally conducting the research in accordance with the University's policies and codes relating to research as amended from time to time. Any C-REC or SREO decision should not detract in any way from the ultimate responsibility of the researcher for all research which they carry out.

- The C-REC may require a researcher to provide an annual progress report on the research project to the C-REC. Any unusual or unexpected events arising in the interim must be reported to the C-REC as soon as possible (see Section 12 below for further information on reporting adverse and unexpected events).

- If there are any changes to the research design or conduct, which might potentially have an impact on the ethical status of the project, the researcher must notify the Chair of the C-REC or the SREO that granted ethics approval for the project. If the Chair or SREEO is of the opinion that the changes are raising serious ethical issues that were not considered in the original review, they may require that the research undergoes further formal ethics review. In this instance, the Chair/ SREO may require that any unauthorised research activity cease until approval is granted.

- A C-REC/ SREO may withdraw its approval and require that the research be suspended or discontinued where unexpected ethical issues arise during the conduct of the study.

7. AMENDMENTS TO APPROVED ETHICS REVIEW APPLICATIONS

An **amendment** is a revision to an approved and ongoing study.

If researchers wish to change any part of the study (e.g. consent forms, procedures, co-investigators, title, funding, surveys, questionnaires, etc.) they must submit an amendment request. Amendments to studies should be changes within the scope of the original study, not new studies that are simply related to the original study. Any resulting new documentation must be included in the application.

Amendments to previously approved research studies must be reviewed and approved by the approving C-REC or SREO before any change to the protocol/study details, consent forms, research instruments or any other change is implemented.

To submit an amendment, applicants need to access the appropriate application within Sussex Direct and select 'Copy Application' at the top of the form.

The original title shall be manually prefaced with 'AMENDMENT' and a succinct overview of requested changes will be entered into the Project Description. All supporting documents (e.g. consent form etc.) will feature updated version numbers and dates.

The Amendment will be submitted for review as per the ethics review process indicated above. The C-RECs will have specific processes for handling such applications and deciding whether they require review by one or multiple reviewers, or the Chair.

8. PROCEDURES FOR RESEARCH GOVERNANCE IN HEALTH AND SOCIAL CARE

8.1 Research involving human participants

The Health Research Authority (HRA) *UK Policy Framework for Health and Social Care Research* (2017) (states that formal independent research ethics review must be undertaken for all health and social care research[15]. NHS Ethics approval must be obtained from the HRA and an appropriate NHS Research Ethics Committee (REC) for any research proposal (including student projects) which involves:-

- 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;
- NHS staff (normally HRA approval only)
- 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 **human tissue** of past and present NHS patients;
- foetal material and IVF involving NHS patients; and
- the recently deceased in NHS premises or facilities.

8.2 Sponsorship

Sponsorship of Research

If you are a member of University staff, or a postgraduate or masters student, undertaking research that meets the criteria set by the Health Research Authority and the *UK Policy Framework for Health and Social Care Research*, notably:

- research involving NHS patients or service users, (including procedures covered by the Human Tissue Act [16]involving tissues or organs) (see also section 8.6 below), NHS facilities or staff *or*
- research that falls within the definition of Clinical Trials for Investigational Medicinal Products (CTIMPs) or medical devices for which clear legal responsibilities must be assumed by law[17],

then formal sponsorship from the University or another appropriate body will need to be sought as a condition of applying for the necessary ethics approval from the HRA / an **NHS Research Ethics Committee**.

What is Sponsorship?

'The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial

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http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/.

[16] The Human Tissue Act 2004 - http://www.legislation.gov.uk/ukpga/2004/30/contents

[17] The Medicines for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

research (The employer or funder is not automatically the sponsor; they explicitly accept the responsibilities of being the sponsor)'[18].

For studies requiring a sponsor, Chief Investigators are required to identify and obtain approval from an appropriate sponsor. Where a research project or a trial is led by a member of University staff, the University will consider acting as sponsor, in principle, under the Health Research Authority's Research Governance Framework[19] and the Clinical Trials Regulations[20]:

The HRA[21] does not permit students below masters level to act as Chief/Principal Investigator. Below doctoral level study, student 'stand alone' research is highly restricted. Students and supervisors are advised to make use of the HRA's 'student research toolkit'[22]

8.3 Sponsorship Sub-Committee

The Sponsorship Sub-Committee (SSC) has responsibility for formal oversight to all forms of sponsored research

- acceptance of Sponsorship (*after recommendation from the PSRP - see below*)
- amendment requests
- protocol deviations/ breaches of Good Clinical Practice (GCP)
- Serious Adverse Event (SAE) notifications
- reports to NHS Research Ethics Committees (RECs)

When is it appropriate for the University to Sponsor?

For all research projects undertaken by a member of University of Sussex staff or student registered at the University of Sussex (including BSMS) for which no prior agreements have been established that a NHS Trust is more appropriate to sponsor.

When is it appropriate for the University to decline to sponsor a research project?

- When the Principal/Chief Investigator, Clinical Investigator or Research Supervisor is not substantively employed by the University of Sussex
- When the student is not registered at the University or does not fulfil HRA requirements to act as a Chief Investigator
- When it has been agreed that it would be more appropriate for the relevant NHS Trust to act as sponsor
- Any other reason (be it academic, legal, financial, liability, insurance, risk or governance) under which it would not be appropriate for the University to do so.

    Each application for sponsorship is considered on a case-by-case basis.

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[18] https://s3.eu-west-2.amazonaws.com/www.hra.nhs.uk/media/documents/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf, pp 18-19

[19] http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/
[20] The Medicines for Human Use (Clinical Trials) Regulations 2004 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made
[21] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/

[22] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/student-research/student-research-toolkit/

What is the process for applying for University Sponsorship?

8.4 Pre-Sponsorship Review Panel (PSRP)

Applications for University Sponsorship must be submitted to the **Pre-Sponsorship Review Panel** (PSRP) which meets monthly[23]. The PSRP brings together reviewers from the University of Sussex, University of Brighton, University Hospitals Sussex NHS Foundation Trust and Sussex Partnership NHS Foundation Trust to advise on new applications for sponsorship.

Meeting dates for the PSRP are published on the Brighton and Sussex Medical School's web pages[24].

All applications are considered on a case-by-case basis with the opportunity for the PSRP to take further expert and specialist advice if questions remain after assessment of risk.

Once the PSRP is satisfied that the application meets the necessary standards, it makes a recommendation to the Sponsor (the University).

> **Applicants should check
> http://www.sussex.ac.uk/staff/research/governance/sponsorship/ssc#Prep to ensure that they are aware of specific requirements for the Sponsor that are additional to those of the SSC. **

The majority of studies that are reviewed by the PSRP will be accepted for sponsorship (after receiving recommendation from the Panel) by **Chair's Action** between SSC meetings. *Exceptions* to this are:

> • Applications for clinical trials of investigational or medicinal products (CTIMPs)
> • Applications for research tissue banks (RTBs)
> • Basic science studies requiring specific medical supervision and oversight requiring the University's Clinical Trials insurance extension
> • Any other studies identified as leading to non-standard risks or additional liabilities to the Sponsor (typically invoking additional insurance or specific risk mitigation measures)

Once sponsorship has been granted, the applicant may apply for the necessary external approvals through the HRA and NHS Research Ethics Committee approvals process.

In return for the University providing sponsorship, the study's Chief Investigator and Investigators have clearly defined responsibilities (see *annex E* of this SOP) set out by the *UK Policy Framework for Health and Social Care Research* .

What is HRA Approval?

HRA Approval brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent ethical opinion by a Research Ethics Committee (REC) so that you only need to submit one application. It applies where the NHS organisation has a duty of care to participants, either as patients/service users or NHS staff/volunteers.[25]

Before applying for sponsorship and the submission process

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[23] https://www.bsms.ac.uk/research/support-and-governance/pre-sponsorship-review-panel.aspx
[24] http://www.sussex.ac.uk/staff/research/governance/sponsorship/applysponsorship
[25] http://www.hra.nhs.uk/about-the-hra/our-plans-and-projects/assessment-approval/

Applicants should consult the *Pre-Sponsorship Review Panel Document Submission Checklist* [26]carefully before starting their application to ensure the appropriate documentation is submitted for Sponsorship review.

If you are unsure whether you need sponsorship or who is the appropriate sponsor for your project or study, please email researchsponsorship@sussex.ac.uk .mailto:

8.5 HRA Approval of capacity and capability for NHS sites to participate in studies

As part of the HRA approval process, research sites identified in the IRAS form are required to accept or reject their role that has been identified by the Chief/Principal Investigator. The use of Statements of Activities and Schedules of Activity templates (submitted with IRAS forms) allow information to be considered efficiently and in a consistent manner[27].

Local R&D management approval is required at each NHS Trust site relevant to the project, before research can begin. An application for R&D management approval is made alongside the HRA process (via the online IRAS form).

8.6 Research with Human Tissue

The Human Tissue Act (2004) (HT Act) is the legislative framework which governs the storage and use of relevant material from the living and the removal, storage and use of relevant material from the deceased, for a scheduled purpose.

The Act focuses on both consent and licensing, making consent fundamental to the removal, storage and use of human tissue for certain scheduled purposes.

The University has four Human Tissue Licences.

- HTA Research Licence (12561) : Brighton and Sussex Medical School
- HTA Anatomy Licence (12098) : Brighton and Sussex Medical School
- HTA Research Licence (12119) : Schools of Life Sciences (including Psychology)
- HTA Public Display Licence (12687) - Brighton and Sussex Medical School

Relevant material, as defined by the HT Act, is material derived from a human body, other than gametes,* which consists of or includes cells (including bodily waste products).

The following are excluded from the Act:

- Hair and nail from the body of a living person
- Embryos outside the human body*
- Cell lines and other material created outside the human body
- Any sample that has been processed to render it acellular (e.g. serum and plasma)
- *Regulated by Human Fertilisation and Embryology Act 1990

A supplementary list of relevant material[28] is available from the Human Tissue Authority[29] and in *Annex D* of this document. This list is neither exhaustive nor exclusive. Potential users of human tissue

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[27] https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/

[28] https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

are asked to seek guidance from Human Tissue Authority where classification of human tissue is unclear.

Any researcher planning to work with Human Tissue is required to consider the Standard Operating Procedures relative to the licence that they will be working under and consult with the relevant contacts identified on the [University Human Tissue page](#)[30].

8.7 Social Care Research (with Adults)

If you propose to carry out research in England which involves adult social care practitioners, adult social care clients and / or social care resources, then your project is governed by *UK Policy Framework for Health and Social Care Research*[31]. The framework includes any person involved in health and social care research: participants, principal investigators and researchers, host organisations, funders, and managers. It includes research undertaken by industry, charities, research councils, universities, and NHS staff. Any such research will require review from the National Social Care Research Ethics Committee.

The framework requires research proposals to be reviewed across the five 'domains' of research governance:

- ethics
- science
- information
- health and safety
- finance (and value for money).

Currently, only *adult social care* is formally covered by the *UK Policy Framework for Health and Social Care Research*, although some Councils have chosen to implement the framework corporately and the Department for Education and the Association of Directors of Children's Services recommend the UK Policy Framework as good practice.

Staff and students who wish to carry out research in this context will require University Sponsorship.

8.8 Submitting Requests for Amendments to sponsored studies

Requests for amendments to previously approved University Sponsored projects must be submitted for University review and approval by the Sponsorship Sub-Committee (SSC) for Sponsorship to remain valid **before** being sent to the HRA.

In the first instance, the PI is required to establish whether the amendment is *substantial* or *non-substantial.*

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[29] https://www.hta.gov.uk/
[30] http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue
[31] Researchers undertaking such work in England, Scotland, Wales and Northern Ireland should make use of the specific Research Governance Framework for the country in which they are working - http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/ . In the course of 2017, however, a revised UK wide Research Governance Framework is due to be launched replacing the current document.

A **substantial amendment** is 'an amendment to the terms of the application, or to the protocol or any other supporting documentation, that is likely to affect to a significant degree:

- the safety or physical or mental integrity of the subjects of the study;
- the scientific value of the study;
- the conduct or management of the study; or
- the quality or safety of any investigational medicinal product used in the trial.

A completed HRA Amendment Tool [32]should be completed and submitted with any supporting documents (updated study documents) to researchsponsorship@sussex.ac.uk .

Substantial amendments are reviewed by SSC meetings (approximately once every six weeks)

Examples of **non-substantial amendments[33]** include

- minor changes to the protocol or other study documentation, e.g. correcting errors, updating contact points, minor clarifications;
- changes to the chief investigator's research team changes to the research team at particular trial sites (other than appointment of a new principal investigator in a CTIMP);
- changes in funding arrangements;
- changes in the documentation used by the research team for recording study data; changes in the logistical arrangements for storing or transporting samples;
- inclusion of new sites and investigators in studies other than CTIMPs;
- extension of the study beyond the period specified in the application form

A completed HRA Amendment Tool [34]should be completed and submitted with any supporting documents (updated study documents) to researchsponsorship@sussex.ac.uk .

In most circumstances, non-substantial amendments can be approved by Chair's Action between meetings of the SSC and are approved within two to three days of receipt.

Subsequent steps

After sponsor approval, the CI should submit the amendment request to the HRA via the online amendments submission portal. Full details are available on: https://www.myresearchproject.org.uk/help/hlpamendments.aspx

8.9 Annual Progress Reports to NHS Research Ethics Committees

Principal Investigators are responsible for ensuring that the Sponsor (researchsponsorship@sussex.ac.uk) receives a copy of Annual Progress Reports to the NHS REC that approved their study[35] in accordance with the Conditions of Sponsorship.

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[32] https://www.myresearchproject.org.uk/help/hlpamendments.aspx

[33] http://www.hra.nhs.uk/resources/after-you-apply/amendments/substantial-and-non-substantial-amendments/

[34] https://www.myresearchproject.org.uk/help/hlpamendments.aspx

9. RESEARCH INVOLVING VULNERABLE ADULTS AND CHILDREN

NOTE: Research involving vulnerable adults and children should not always be considered high risk. Particular care must be taken when researching these groups but this should not discourage or obstruct research.

9.1 Safeguarding

All researchers should ensure that they are familiar with the University's Safeguarding Policy and its Referral Pathway for raising any matters should they arise.

https://www.sussex.ac.uk/safeguarding/

9.2 Disclosure and Barring Service (DBS) Enhanced Check

It is a requirement under the Exceptions Order to the Rehabilitation of Offenders Act (1974)[36] that those undertaking work, including research, with children or vulnerable adults undertake an Enhanced Disclosure with the Disclosure and Barring Service (DBS). Further guidance is available on the research governance website.

9.3 Research involving vulnerable adults

- Consent procedures should be explored with vulnerable people (for example those with mental incapacity, in care, at risk or involved in illegal activities). Informed consent should be actively and directly sought from those with learning difficulties or sensory disabilities, and wherever possible should not depend on carers or relatives; to this end, use of alternative forms of communication such as signing, symbols or Braille should be maximised and advice sought on the appropriate ways to communicate with that group.

- Consent should be constantly monitored, for example, through non-verbal cues – to check that participants have clearly understood the information that was provided to them.

- Anonymity and confidentiality are likely to be particularly important and sensitive.

- Researchers need to make their duty to disclose clear that disclosures by a participant suggesting serious danger to the participant or others, cannot be treated confidentially by the researcher.

- Where information given in a research context suggests that there is a threat of serious harm to the subject or others, researchers should disclose this to the relevant authorities, but inform the participants and their guardians/responsible others of their intentions and reasons for doing so. This may include actual or planned criminal activity. In general,

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[35] http://www.hra.nhs.uk/resources/during-and-after-your-study/nhs-rec-annual-progress-report-forms/

[36] http://www.legislation.gov.uk/uksi/1975/1023/contents/made

there is no legal obligation to report an offence (except in certain terrorism and money laundering cases), but careful consideration of the Serious Crime Act 2007[37] should be undertaken by the researcher. This Act deals with offences such as assisting or encouraging an offender, which may impose a duty to act in order to avoid liability[38]. Contemporaneous notes should be kept in case a complaint arises.

- Researchers should proactively make themselves aware of relevant services (e.g. counselling), in case support needs emerge during the research.

9.4 Research involving children

- The principles outlined above also apply in the case of children and young people.

- Children (defined as those aged under 18) will need particularly careful consideration with respect to establishing and monitoring consent, the role of gatekeepers, the use and communication of findings and the potential disruption (emotionally or practically) caused by the research itself.

- Informed consent from children and young people should be actively and directly sought using communication methods that maximise their understanding of the research.

- Informed consent for research with children under 16 must also be obtained from those with parental responsibility for them in law, adhering to the same principles outlined above. For children aged between 16 and 18, the ethics review process must take into account the context of each research project and whether the young people involved can be expected to have sufficient understanding to make an informed choice.

- Disclosure of information suggesting serious harm to the child or others should be addressed as indicated in the guidelines above on vulnerable people.

- Participation in the research should be made as rewarding and enjoyable as possible.

  Interviewing children should either be undertaken by two researchers or in areas where the researcher and child are not entirely alone to protect the researcher as well as the child.

- Consider the gender of interviewers where appropriate, for example in research involving children who have been sexually abused.

- Feedback on the findings should be given in ways that are meaningful to the participants.

- The Data Protection Act (2018) requires parental consent for the taking of data

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[37] https://www.legislation.gov.uk/ukpga/2007/27/contents

[38] The British Psychological Society, the British Sociological Association and the UK Data Archive are examples of three organisations that have offered guidance and statements on this matter. The British Psychological Society, for example, in its Professional Practice Guidelines offers the following advice about disclosure that is in the 'public interest' "In exceptional circumstances, disclosure without consent, or against the client's expressed wish may be necessary in situations in which failure to disclose appropriate information would expose the client, or someone else, to a risk of serious harm (including physical or sexual abuse) or death."- http://www.bps.org.uk/sites/default/files/documents/generic_professional_practice_guidelines.pdf, p.10

from children for the purposes of research. The legislation considers the age of 13 to be the earliest age at which consent to take part in research can be taken[39].

9.5 Research with children in schools

Applicants wishing to work with children in schools should consult and prepare their applications in alignment with the University's *Guidance for obtaining consent for research with child participants in schools*.[40]

Although researchers may approach schools in the first instance for an 'in principle' agreement to take part in research, the formal acceptance that research can take place within a school by the head-teacher (or similar) can only occur *after* C-REC ethics approval has been granted and the relevant supporting documents provided.

10. SCIENTIFIC PROCEDURES AND RESEARCH INVOLVING NON-HUMAN ANIMALS

Scientific procedures involving non-human animals, including research on animals and the breeding of animals for use in research is regulated by the 1986 Animals (Scientific Procedures) Act (1986). This statute requires that all establishments involved in such activities should establish and maintain a local ethics review process.

The University has a committee set up for this purpose, the Animal Welfare and Ethics Review Body (AWERB) to provide review and ethics advice to the Certificate Holder and to promote ethical awareness of animal welfare issues leading to the widest possible application of the 3Rs – reduction, refinement and replacement. The University website carries further details on the principles that the AWERB follows to make its decision[41]. Researchers should also be aware that the University is a signatory to the Concordat on Openness on Animal Research.[42]

This committee also provides a review process for any proposal for research involving animals that is *not* regulated by this Act. In these cases, the committee will decide whether such projects are ethically acceptable to the University, and ensure that all relevant regulations are compiled with, and that all potential harms to animals, however mild, are reduced to a minimum.

Researchers proposing to carry out a project that involves animals should seek advice from their Head of School, supervisor, or the Research Governance Officer.

The Research Governance Officer should be contacted for information about the formal internal processes to be followed for applying for ethics review.

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

40 https://www.sussex.ac.uk/webteam/gateway/file.php?name=guidance-for-obtaining-consent-for-research-with-child-participants-in-schools-241014-soprgo02.pdf&site=377

[41] http://www.sussex.ac.uk/staff/research/governance/erp_overview/animals
[42] http://concordatopenness.org.uk/

11. HEALTH AND SAFETY IN RESEARCH

The health and safety of staff, students and visitors is of paramount importance to the University. It is important that the University operates effectively and allows its staff, students and visitors to undertake their activities without detriment to their health, safety and wellbeing.

Application of good practice in health and safety is recognised as being a key component in achieving high quality teaching and research. It is also acknowledged that failings in health and safety could not only have a harmful impact on the University's ability to conduct its business, but also harm our reputation. The undertaking of appropriate risk assessments covering possible dangers to both participants and researchers is vital to protecting and maintaining this reputation and is also a vital part of good research practice that is expected by the institution.[43]

Good health and safety practice will be achieved if staff, students and their visitors give their full support to the University in ensuring that teaching, research, events, activities etc. are carried out in accordance with relevant regulations, policies, local rules and guidance documentation.

The Health, Safety and Wellbeing Team is available to support, advise and guide you with any Health & Safety queries/advice that you might require[44].

12. DATA MANAGEMENT AND THE HANDLING OF PERSONAL DATA

The collection, use and sharing of data in research requires that both ethical and legal obligations are followed.

Researchers have an ethical duty to ensure that when collecting data, participants give informed consent as to how their data will be stored, preserved and ultimately destroyed.

Researchers should set out clearly how confidentiality will be maintained and give sufficient thought as to whether the consent that they seek will be appropriate for any later use of the data.

Informed consent should be appropriate to the participant, the research activity and the nature of the data being gathered.

Consent should be granular and specific to the information or data taken and the form of media being used.

12.1 The Data Protection Act (2018) and (UK) General Data Protection Regulations – Personal and Special Category Data

All researchers are required to understand and comply with the Data Protection Act (2018)[45]and (UK) General Data Protection Regulations, referred to collectively as data protection legislation.

The legislation applies to '**personal data'** which is defined as any information relating to an identifiable person who can be directly or indirectly identified in particular by reference to an identifier.

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[43] http://www.sussex.ac.uk/hso/hsoatoz
Under the University's Code of Practice for Research, failure to 'follow accepted procedures or to exercise due care in carrying out responsibilities for avoiding unreasonable risk or harm' are grounds for initiation of the Procedure for the Investigation of Allegations of Misconduct in Research.
https://www.sussex.ac.uk/webteam/gateway/file.php?name=code.pdf&site=377
[44] http://www.sussex.ac.uk/hso/index
[45] https://www.sussex.ac.uk/ogs/policies/information/dpa/processingdata

(a) from those data, or

(b) from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller[46], and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual.

In addition the legislation has provisions for:

> **'Special category data'** -   Special category data are defined in the legislation as information about a an individual's :

- race;
- ethnic origin;
- politics;
- religious or philosophical beliefs;
- trade union membership;
- genetics;
- biometrics (where used for ID purposes);
- health;
- sex life; or
- sexual orientation.

Each of which are specifically protected and must be treated with the utmost care and sensitivity in the course of research.

Personal **data relating to criminal convictions or offences** can only be processed if it occurs under a lawful basis (Article 6) and either legal authority or official authority for the processing under Article 10[47]. Ethics permissions for research in prisons or other parts of **Her Majesty's Prison & Probation Service** will need to be obtained (after Sponsorship is granted (Section 8 of this SOP)[48]. Under the same principles, formal approval is needed from the **HM Courts and Tribunals Service** to carry out research in these settings[49].

Researchers planning to use special category data or criminal convictions data are required to make sure that it is taken with explicit information provided to participants about how it will be used, stored and ultimately destroyed in compliance with data protection legislation. This will include technical safeguards (such as encryption) to ensure its security[50] and researchers should refer to the University's Information Classification and Handling Policy and Information Classification and Handling Matrix.

Where researchers intend processing special category or criminal offence data on a large scale (typically >1,000 data subjects) a Data Protection Impact Assessment (DPIA) may be required. Further guidance, including a DPIA screening tool, is available on the University's Data Protection web-pages (https://www.sussex.ac.uk/ogs/policies/information/dpa).

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[46] 'Data controller' means a person who (either alone or jointly or in common with other persons) determines the purposes for which and the manner in which any personal data are, or are to be processed. 'Data processor', in relation to personal data, means any person (other than an employee of the data controller) who processes the data on behalf of the data controller.

[47] https://ico.org.uk/for-organisations/guide-to-data-protection/guide-to-the-general-data-protection-regulation-gdpr/lawful-basis-for-processing/criminal-offence-data/

[48] https://www.gov.uk/government/organisations/her-majestys-prison-and-probation-service/about/research

[49] https://www.gov.uk/guidance/access-to-courts-and-tribunals-for-academic-researchers

[50] The University's IT Services Division should be contacted for advice on good practice in the encryption and safe management of data on the institutional network or approved storage resources: http://www.sussex.ac.uk/its/

12.2 Data Protection Principles

The Data Protection Act 2018 and (UK) General Data Protection Regulations require that the University and all those who work within it (staff and students who act as 'data processors') process all personal data in accordance with the six **Data Protection Principles**

When processing personal information data must be:

1. **Lawful, fair and transparent**
   Lawful: processing must meet the tests described in the legislation
   Fair: what is processed must match up with how it has been described
   Transparency: tell the subject what the processing is for

2. **Limited in Purpose**
   Personal data can only be obtained for "*specified, explicit and legitimate purposes*"

3. **Minimised for processes purposes**
   Data collected on a subject should be *"adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed"*

4. **Accurate**
   Data must be *"accurate and, where necessary, kept up to date"*

5. **Limited in storage**
   The regulator expects personal data is "*kept in a form which permits identification of data subjects for no longer than is necessary*". In summary, data no longer required is removed

6. **Subject to appropriate storage arrangements**
   The legislation requires processors to handle data "*in a manner that ensures appropriate security of the personal data*",   including protection against unauthorised or unlawful processing and accidental loss, destruction or damage

The University processes personal data for research purposes in relation to its public tasks and legitimate interests. These legal bases for processing are regularly reviewed and balanced against individual rights and freedoms..

Further information about Data Protection and the University can be found on the University's Planning, Governance and Compliance web pages -
https://www.sussex.ac.uk/ogs/policies/information/dpa

12.3 University Data Management Policy

The University's requirements for Data Management are set out in the *Research Data Management Policy*[51].The policy sets out the institutional standards to be followed for managing research data including non-anonymised personal data.

12.4 Data Breaches

Under data protection legislation, researchers are responsible for reporting actual or suspected

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[51] https://www.sussex.ac.uk/webteam/gateway/file.php?name=rdmpolicy.pdf&site=269

breaches of data security to the University's Data Protection Officer[52] at the *earliest possible opportunity* who will then assess whether the Information Commissioner's Office need to be notified. As an institution, the University is required to report breaches within 72 hours.

The Information Commissioner's Office defines a data breach as 'a security incident that has affected the confidentiality, integrity or availability of personal data. In short, there will be a personal data breach whenever any personal data is lost, destroyed, corrupted or disclosed; if someone accesses the data or passes it on without proper authorisation; or if the data is made unavailable, for example, when it has been encrypted by ransomware, or accidentally lost or destroyed.'[53]

12.5 Funder Data Management Requirements

Researchers should ensure that they understand the requirements of research funders' data sharing and data management policies, notably in relation to open access[54]. These should be outlined in ethics review applications to C-RECs.

In the event of any potential conflicts, legal, ethical and commercial constraints should be flagged so that they are understood within the ethics review process and support needs identified for any contracts or specialist advice.

In the absence of any specific external requirements, researchers should ensure compliance with University of Sussex data management policies[55]

12.6 Data and Records Management within the NHS

In addition to requirements to work within data legislation, researchers who handle NHS patient records and data are responsible for understanding and working to standards and procedures established by partner NHS trusts. In the event that such policies are not available, the 'Confidentiality: NHS Code of Practice' s (2003)[56], published by the Department of Health, serves as a reference point for legal requirements and professional best practice across the whole organisation.

Special category data taken by the NHS for the purposes of patient care and then shared for University research should be managed with the utmost care and all efforts should be taken to avoid any such data being processed or stored in University systems or held in paper form. When data of this type is required for research, the highest standards of security involving digital encryption and the use of locked filing cabinets behind locked doors (or equivalent) should be used following approval by a research ethics committee. Wherever possible, the use of anonymised or pseudo-anonymised data only within the University (with the NHS partner holding the 'key' to the personal identifiers) is the preferred way of working to protect the interests of all parties. Researchers should provide as much detail as possible in protocols and to participants about how such data will be taken, transferred, stored and finally deleted whilst preventing possible data breaches or data loss.

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[52] dpo@sussex.ac.uk

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

[54] https://www.dcc.ac.uk/resources/data-management-plans/funders-requirements

[55] https://www.sussex.ac.uk/library/researchdatamanagement/policies

[56] http://webarchive.nationalarchives.gov.uk/20161101131024/http://systems.digital.nhs.uk/infogov/codes/confcode.pdf

12.7 Research Data Storage at the University of Sussex

All digital research data should be password protected and backed up in case of hardware or network failure. The University's IT Services (ITS) helpdesk can advise on best practice to ensure appropriate data security and the University's Information Classification and Handling Policy and Information Classification and Handling Matrix provide a framework for safeguarding University information.

University approved digital storage should be used by default- namely Home Share (N drive), Box or OneDrive. For funded research. ITS Research Support can assist and advise on additional drive space and back-up services[57].

The use of pen drives and portable hard drives is to be avoided as much as possible for any personal data unless adequately encrypted to protect their contents in the event of theft or loss[58].

The University has subscriptions to web-based survey and questionnaire services available to all researchers such as Qualtrics. ITS can advise on how to set up an account. The use of non-approved web-based survey tools and platforms carries strong risks of non-compliance with data legislation and should be strictly avoided.

Any personal data or records held for research purposes in hard copy (paper) should be kept securely in a locked filing cabinet (or similar) in a secure place. The researcher should make firm plans for the destruction of the documents on the completion of research. The University's *Master Records Retention Schedule*[59] and *Records Management Policy* provides guidance on how long research data and records should be kept before they are destroyed[60].

13. APPLYING FOR RESEARCH GOVERNANCE AND ETHICS REVIEW FOR HEALTHY VOLUNTEER STUDIES REQUIRING MEDICAL SUPERVISION

Any studies that require medical supervision for assuring the safety of health volunteer research participants shall be reviewed by the Brighton and Sussex Medical School Research Governance Ethics Committee (RGEC)[61]. This typically (but not exclusively) applies to studies involving the administration of prescription and controlled drugs, herbal supplements with significant side-effects or large amounts of alcohol. This is likely not to apply to the use of common non-prescription drugs used as per approved conditions of use, safe quantities of alcohol or food stuffs. In such studies the University expects suitable risk assessment to have taken place and to be provided as supporting evidence to the reviewing ethics committee.

The granting of approval for such studies, notably in respect of ensuring that medical supervision is appropriate and that safety aspects have been thoroughly considered, is subject to very high levels of

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[57] http://www.sussex.ac.uk/library/researchdatamanagement/store
[58] https://www.sussex.ac.uk/its/services/research/researchdata/datastorage
[59] https://www.sussex.ac.uk/ogs/information-management/records-management/rm-policy

[60] https://www.sussex.ac.uk/ogs/information-management/records-management
[61] https://www.bsms.ac.uk/research/support-and-governance/governance-and-ethics/index.aspx

scrutiny. From an insurance perspective, the provision of medical cover for research must be approved **strictly on a case by case basis** (even if the applicant or the named medical supervisor) is substantially employed in a medical role.

The following should be provided as supporting documents for ethics and research governance review:

- A full and detailed research protocol covering all aspects of the study
- Completed Delegation of Duties Log (with signatures)
- CVs of research team and medical supervisor(s)
- Evidence of relevant training (e.g. GMC recognition, appropriate CPD and Good Clinical Practice certificates)
- Proof from the MHRA that the study is not a clinical trial[62]

The RGEC may request further documents and proofs as required to understand the study and to gain assurance on its safety and the ethics that underpin it. As part of the conditions of approval, the Committee may request that the study be fully audited. PIs should ensure that they set up and maintain a Trial Master File[63] as evidence that all protocols have been followed.

Queries about this process should be addressed to the Research Governance Officer in the first instance.

A copy of the SOP and Delegation of Duties Log is in the appendix of this document.

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[62] https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk
[63] http://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial

14. EXTERNALLY FUNDED PROJECTS – WHEN TO UNDERGO ETHICS REVIEW

In situations where the Principal Investigator (PI) is applying for research funding, it is usually not necessary to obtain formal ethics approval at the funding application stage, as funders (e.g. ESRC) do not normally require this until an award has been notified. The PI, however, must ensure that all ethical issues arising from the research have been considered at the time of application, with clear indications as to how those issues will be addressed and reviewed[64]. The PI should consider the time that will be taken to gain ethics review (for high risk projects this will be *at least* one month) and the proposed start date for the project should take this into account.

14.1 Research led by another UK HEI or research organisation

If Sussex is collaborating with another UK HEI or research organisation who is the lead partner, then the expectation is that the recognised and appropriately constituted ethics review procedure in place within the other partner should apply to the research. Characteristics of being appropriate will include public statements of endorsement of the *Concordat to Support Research Integrity*[65] or terms of reference that align to recognised standards such as the ESRC Framework for Research Ethics[66], the AFRE Framework of Policies and Procedures for University Research Ethics Committees[67] or the HRA's Governance Arrangements for Research Ethics Committees (GAfREC)[68].

As a general principle, as long as the project does go through the other research partner's ethics review procedure, it will *not* need to be reviewed through University of Sussex ethics procedures.

However, there may be circumstances where a local review may be necessary, for example, if the recruitment of participants is largely or entirely based at Sussex.

In either case, a copy of the lead institution's ethics approval should be available as part of the project documentation and have been received before research activity at the University of Sussex can commence. Contact the Research Governance Officer (rgoffice@sussex.ac.uk) with any queries.

Consideration of possible equivalence of ethics review by non UK HEIs or research organisations will take place on a strictly case by case basis by contacting the Research Governance Officer.

15. PROCEDURES FOR APPEAL AGAINST A C-REC OR SCHOOL ETHICS REVIEW DECISION

The first process of appeal should be an informal discussion with the C-REC Chair, or in the case of a School review, with the Supervisor or the School Ethics Officer. If an informal oral resolution is not successful, then a more formal appeal process should be initiated which will allow for the case to be escalated to the next level of ethics review (i.e. School-level up to C-REC; C-REC up to REIC).

The REIC will not hear appeals from researchers against the decisions through School or C-REC ethics review processes until more informal remedies have been exhausted. The REIC will, in exceptional cases, consider and make decisions on behalf of the University on specific cases, appeal or on other matters. The REIC is particularly concerned with circumstances where a decision on ethics or research governance in general has potential legal implications for the University or wider effects as a matter of

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[64] Researchers are advised to ask that ethical issues are part of any internal peer review of research plans that occur prior to submission of funding proposals.
[65] https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-research-integrity
[66] http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/
[67] https://www.arma.ac.uk/research-ethics/Framework-of-policies-and-procedures.pdf
[68] http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/

principle or precedence.

16. PROCEDURES FOR REPORTING ADVERSE AND UNEXPECTED EVENTS

PIs and supervisors must report any adverse (undesirable and unintended) and unexpected events arising out of the research. This should be done via the standard reporting document (available on the Health & Safety website) and submitted to the Head of School and the C-REC which granted approval to the project. In the case of Undergraduate / PGT research, the form should be sent to the Supervisor and School Research Ethics Officer. This should be done within one week of the event. In the case of a serious adverse event, the PI must immediately stop the research and alert the Chair of the relevant C-REC within 24 hours of the occurrence. In research that has significantly greater risks with possible risks to the health of participants, C-RECs may require swifter and more specific alerting procedures to protect those who may be concerned.

The Health, Safety and Wellbeing team also review reported events and incidents and will advise where required. The team is happy to provide advice to researchers needing guidance in good practice when planning research.

The primary goal of recording adverse and unexpected events during research is to provide a learning exercise for both researchers and ethics committees, and Schools are asked to encourage reporting of problems during research.

17. MONITORING OF ETHICS REVIEW PROCESSES

The University recognises that the definition and manifestations of research governance issues change continuously. In this light Schools, through their designated School Ethics Officers, and C-RECs, must conduct an annual review of their ethics review decisions and procedures. Schools will report to their C-REC, and C-RECs to REIC. The REIC will consider these reports, offering advice and recommendations as appropriate and report to Senate on any significant matters.

The Research Governance Office, may, on behalf of REIC request that a random sample of researchers who have received ethics approval undertake a self-audit to report on any deviations or unexpected events to have arisen in the pursuit of their research

17.1 Monitoring at School-level

The University requires all Schools to ensure administrative processes are put in place to manage and monitor ethics review of UG and PGT projects. This will include reviewing the following information:

- number of projects submitted for ethics review by UG and PGT students;
  - number of projects approved;
  - number of projects referred to a C-REC for review;
  - record of any significant issues arising, including adverse and unexpected events or potential research governance policy matters.

Schools are asked to provide a summary report of this information to their parent C-REC, at the end of each academic year.

17.2 Monitoring of C-RECs

The University requires that each C-REC ensures that administrative processes are put in place to manage and monitor the committees ethics review decisions. This will include reviewing the following information:

- number of projects approved / approved with major amendments / or rejected;
- date of approval;
- length of the approval;
- summary of any significant issues arising, including adverse and unexpected events or potential research governance policy matters.

18. ALLEGATIONS OF MISCONDUCT

Any allegations of misconduct are taken very seriously by the University, and are dealt with through a separate process. The *Procedure for the Investigation of Allegations of Misconduct in Research* sets out the University's policy and processes in this area[69].

19. LEGAL ISSUES

The role of the University ethics review process is to ensure that proposed research projects meet ethical standards; it is not to vet them for legality. However, if an SREO, a C-REC member conducting a low-risk review, or a C-REC as a whole, has reason to believe that a proposed research project, although ethically acceptable in other respects, may involve either a risk of a breach of the law, or may uncover breaches of law by participants in the study then the Chair should seek legal advice on the issues through the Research Governance Officer in the first instance (rgoffice@sussex.ac.uk).

20. CONTRACTS AND INTELLECTUAL PROPERTY (IP)

The Contracts & IP team is responsible for providing contracts and legal support on research related contracts to the University's Research & Enterprise Services division and individual researchers.

Contract types dealt with by the Team include:

- confidentiality agreements
- material transfer agreements
- collaboration agreements
- memorandums of understanding
- tenders
- studentships
- grants
- EU agreements
- clinical trial agreements
- Intellectual Property Rights

This includes providing advice and drafting, reviewing and negotiating the contracts. The team ensures that the University's research related contracts do not contain unacceptable financial and legal risks and meet the needs of both the University and its researchers.

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[69] http://www.sussex.ac.uk/staff/research/rqi/policy/research-policy

To be valid, contracts and agreements must be signed by appropriate signatories on behalf of the University in accordance with the Scheme of Delegation set out in the Financial Regulations

Researchers may not sign legal agreements on behalf of the University.

The Contract and IP team can be contacted via Contracts.Instructions@sussex.ac.uk .

21. OVERSEAS RESEARCH, TRAVEL AND INSURANCE

Researchers undertaking studies overseas should seek to understand the ethical and research governance requirements of the countries that they will be visiting. This may include licences and permissions to use certain equipment, visit specific areas or obtain ethics review from local ethics committees if researching government departments (or similar) that need 'gate-keeper' permissions. Due diligence should be undertaken to make sure that all local legal and regulatory requirements are met and that ethics issues are understood and acknowledged.

If a research project involves overseas travel, applicants must complete an *Overseas Travel Safety and Security Risk Assessment* (OTSSRA) form that is available from the University Health, Safety and Wellbeing internet pages. Researchers are required to check and understand Foreign and Commonwealth Office (FCO) travel advice before completion of the form.

Plans to travel to countries with significant risks (as identified by the FCO's travel advice[70]) will require the completion of part 2 of the form, including *authorising signatures* before being submitted. All sections should be completed in as much detail as possible with supporting documents such as:

- itineraries
- specific and detailed risk assessments
- evidence of expert advice
- a researcher CV (showing evidence of relevant prior experience)

Researchers who are visiting countries that the FCO identify as having significant risks may well benefit from taking advice from other researchers or organisations with recent practical experience of the travel to the area. The requirement for completing and submitting an OTSSRA form does not exclude nationals/residents of countries outside the UK who are students or staff at Sussex who are returning to their home country to undertake research.

The Universities and Colleges Employers Associations document, *Responsible research - Managing health and safety in research: guidance for the not-for-profit sector*, is an invaluable starting point in understanding many of the issues that should be considered[71]. It should be noted that the University has significant responsibilities for staff and students that are no less important when non-UK citizens are travelling to their home countries whilst undertaking research.

To be valid, all OTSSRA forms that have part 2 completed (higher risk travel) need to be seen by the University Insurance Manager who will advise on whether the researcher needs to take out any additional insurance cover[72]. The Health, Safety and Wellbeing team can also give advice on planning

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[70] https://www.gov.uk/foreign-travel-advice
[71] https://uceastorage.blob.core.windows.net/ucea/download.cfm/docid/responsible_research_-_managing_h_s_in_research.pdf
[72] http://www.sussex.ac.uk/finance/services/corporateaccounting/insurance

safe travel overseas[73].

All authorised forms should also be submitted to the relevant School Office for retention and access of contact details whilst away from the University.

A C-REC may withhold ethics approval if it is not satisfied that matters relating to researcher safety have been sufficiently considered[74].

22. MONITORING AND SUPPORT BY RESEARCH GOVERNANCE OFFICER

On-going training and support will be provided by the Research Governance Officer, both in respect of the operation of the system and for staff and students generally. Regular communication with C-REC Chairs and support staff will ensure that new developments / requirements in ethics review are effectively disseminated.

The REIC may decide to undertake random monitoring of a proportion of ethics reviewed projects to understand how ethical aspects of research are being considered throughout the life cycle of studies.

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[73] http://www.sussex.ac.uk/sef/services/health
[74] http://www.sussex.ac.uk/hso/specialist/riskass/fieldworkriskassessment

Annex A: Terms of Reference for Cross-Schools Research Ethics Committees (C-REC)

Key Role:

• to provide independent review of the ethical design of research, on behalf of the University in accordance with the principles and values of the Code of Conduct for Research and the standards of the Concordat to Support Research Integrity and as indicated in the University's ethics review framework

• to review, facilitate and encourage consistently high-quality ethical research in accordance with the standards of good practice across the disciplines of the academic schools represented on the committee.

• to ensure, on behalf of the Research Ethics and Integrity Committee, that good practice is shared and that an understanding of high-quality ethical research practice is valued and recognised as a fundamental quality of a skilled researcher at the University of Sussex.

There will be three Cross-Schools Research Ethics Committees (C-RECs) as follows:

Science and Medicine (2 committees):

• Sciences and Technology C-REC (SCITEC) cluster (covering the School of

Engineering and

Informatics, the School of Life Sciences, the School of Mathematical and Physical Sciences and the School of Psychology).

• Brighton and Sussex Medical School Research Governance and Ethics Committee (BSMS RGEC).

Social Sciences and Arts (1 committee):

• Social Sciences & Arts C-REC (SSARTS) cluster (covering the Business School, the School of Education and Social Work, the School of Global Studies, the School of Law, Politics and Sociology, and the School of Media, Arts and Humanities).

(1) Terms of Reference:

(a)   to follow the requirements laid out in the University's codes and policies relating to research ethics, integrity and to support and facilitate effective research governance within a culture of honesty and respect for participants, the environment and the full range of stakeholders of university research;

(b)   to make recommendations to the Research Ethics and Integrity Committee relating to the procedures and policies for supporting and facilitating ethical research under the auspices of the schools, appropriate to the academic disciplines within the Schools, and in accordance with recommendations made by relevant outside bodies;

(c)   through the relevant School Directors of Learning and Teaching , to conduct a periodic review of School procedures which consider low risk projects (including undergraduate) and to prepare periodic reports on the findings and to keep the effectiveness of its current practice under continuous review.

(d)   to review and approve on an annual basis, the basis on which academic schools organise the oversight of School Research Ethics Officers (SREOs) where more than one is appointed by the Head of School.

(e)   to report on a periodic basis to the Research Ethics and Integrity Committee in a form stipulated by the Research Ethics and Integrity Committee, providing a summary of all reviewed projects;

(f)   to implement review mechanisms for staff and student projects that ensure that research ethics policies are applied in a manner appropriate to such projects and that any associated research governance requirements are identified and dealt with in a manner consistent with the highest standards of research excellence.

(g)   to undertake auditing of a percentage of previously approved studies according to

Research Ethics and Integrity Committee requirements

(h)   to participate and facilitate auditing of the ethics review process across C-REC and across SREOs within the C-REC

(i)   to review and approve any School or cross-School based processes for the review and approval of relevant research projects.

(j)   to keep appropriate records of practices and decisions and to issue a common form of Certificate of Approval which will cover statutory and ethics compliance, research integrity and, where appropriate, sponsor specific requirements.

(k)   to refer cases to the Research Ethics and Integrity Committee that require decision or require advice / opinion.

(2)   Composition:

•   A member of academic faculty distinguished in research (Chair).

•   One (or more) member(s) from each School undertaking research relevant to the Committee, nominated by the relevant Head of School (proportionate to applications reviewed by the cluster).

•   At least one external lay member

•   School Research Ethics Officers (SREO) from the academic schools in the cluster*

•   Additional (non-voting) attendees may be invited by the Chair for meetings or items to ensure an appropriate range of expertise.

*Not all SREOs will act as C-REC reviewers (through full membership of the C-REC) for high risk PGT, undergraduate studies or staff and PGR applications.

The terms of the SREO's reviewing duties, as specified in the letter of appointment, will be agreed by the Head of School, and will reflected in the time allocated within their overall responsibilities.

(3)   Reports to: Research Ethics and Integrity Committee

Annex B - Role Descriptions for Key Ethics Review Personnel

Role Descriptions for Key Ethics Review Personnel

C-REC Chair

Overview of Role

In addition to the key responsibilities set out for C-REC Members (attached), the main purpose of this role is to be Chair to [SPECIFIC C-REC]. The Chair as leader of the C-REC is responsible for the Committee's ethics review function, and ensuring responsive, independent, and informed consideration of the ethical design of research from schools within the cluster. The Chair will also take a lead role in promoting a culture of research integrity across the Schools. The Chair will receive support, and work closely, with the Social Sciences & Arts CREC Research Ethics, Integrity and Governance Administrator, C-REC members and SREOs.

Key Responsibilities:

1. Oversee the consistent and timely management of the C-REC ethics review processes within a culture of honesty and respect for participants, the environment and the full range of stakeholders of University in accordance with the *Code of Practice for Research* and the *Concordat to Support Research Integrity*.

2. Implement review mechanisms for staff and student projects that ensure that University research ethics policies are applied in a manner appropriate to such projects and that any associated research governance requirements are identified and dealt with in a manner consistent with the highest standards of research practice;

3. To be aware of Equality and Diversity and ensure that applicants to the C-REC are treated fairly and equally regardless of age, gender, sexuality, religion, disability or ethnicity.

4. To nominate a Deputy Chair, and to offer ongoing support to the person in this role, ensuring they are able to take over the duties of the Chair when required. In the event that a Deputy Chair is not available, the School that employs the Chair, shall, in the first instance, ensure that cover is available until such time as a new Chair can be formally appointed.

5. Promote the effective working of the C-REC as a cohesive group, providing guidance to members regarding potential conflicts of interest and any concerns which might lead to their disqualification.

6. Identify any training needs for C-REC members, and work with the Research Governance Officer to make arrangements for training provision. Address issues of poor performance from members in the first instance.

7. Organise and Chair a minimum of one physical meeting of the C-REC per year.

8. Provide general advice and guidance to the C-REC Research Ethics, Integrity and Governance Administrator, C-REC members, SREOs.

9. Provide advice and guidance to Supervisors and researchers (staff and students).

10. Support and advise School Research Ethics Officers and receive an annual report from them on School-level ethics review.

11. Where appropriate, assist Heads of Schools in recruitment of new members to the CREC.

12. Sit as an *ex-officio* member of the Research Ethics and Integrity Committee (REIC), attending a minimum of two meetings per year. Provide periodic reports to REIC, summarising the C-REC's and relevant Schools' ethics review activities.

13. Contribute to development, monitoring and review of ethics policies, procedures and processes.

14. Oversee the auditing of a percentage of previously approved studies according to Research Ethics and Integrity Committee requirements.

15. Participate and facilitate in periodic auditing of previously reviewed applications by other C-RECs and across SREOs within the C-REC to assist in the maintenance of consistent standards across the University.

16. Liaise with the Research Governance Officer, to lead development and management of cross school activities and training to promote research integrity within and across schools, and university wide.

17. Produce and ensure dissemination of cross-school specific guidance for faculty and students on research ethics review processes and procedures; support C-REC members and SREOs to do the same tailored for specific schools.

Appointment: by Pro-Vice Chancellor (Research) following nomination by Heads of Relevant Schools.

Tenure: 2 years, renewable for a further term

C-REC MEMBER

LAY C-REC MEMBER
Overview of Role

The main purpose of this role is to carry out independent and informed review of the ethical design of research projects from across those Schools which are relevant to the C-REC, and to bring specific

expertise to the review process from the School that the member represents. The C-REC member will also take a lead role in promoting research integrity and good practice in research ethics across their School, and the University more widely.

Key Responsibilities:

1. To provide independent, competent and timely review of the ethics of proposed research studies from faculty and students within a culture of honesty and respect for participants, the environment and the full range of stakeholders of University research.

2. Ensure that every project which undergoes ethics review, is dealt with fairly and appropriately in accordance with the University's research ethics and governance policies and procedures. Where there may be a conflict of interest, the member should alert the Chair of the C-REC.

3. To be aware of Equality and Diversity and ensure that applicants to the C-REC are treated fairly and equally regardless of age, gender, sexuality, religion, disability or ethnicity.

4. To undertake training and personal development relating to ethics and research integrity upon taking up the role and to attend training provision that is made available annually.

5. To raise with the Chair any ongoing challenges relating to the review of research ethics to help identify any issues that may need to be dealt with as a matter of policy by the C-REC or the Research Ethics and Integrity Committee (REIC).

6. Attend a minimum of one meeting of the C-REC per year.

7. Maintain confidentiality regarding applications, ethics review deliberations, information on research participants, and related matters.

8. To provide *ad hoc* advice to faculty and students within the member's School on the ethical conduct of research and ethics review processes.

9. Encourage a culture within the member's School which recognises the central importance of ethical considerations in the design and performance of research, and provide an avenue for the promotion of initiatives for research integrity.

10. Ongoing contribution to development, monitoring and review of research ethics policies, procedures and processes.

11. Contributing to the C-REC's auditing of returns from researchers relating to previously approved studies.

12. Support the Chair in participating in periodic auditing of previously reviewed applications by other C-RECs and across SREOs within the C-REC to assist in maintaining consistent standards across the University.

13. Contribute to development and management of cross-school activities and training to promote research ethics culture within and across schools, and university wide.

14. Collaboration with C-REC Chair and SREO to produce school specific guidance for faculty and students on research ethics review processes and procedures; liaising with SREO, School based administrative staff and the cluster Research Ethics, Integrity and Governance Administrator to ensure appropriate links from school websites to central ethics website, are established and maintained.

15. Liaise with SREO on all School specific research ethics and governance issues, and with faculty/supervisors on within- school training and development needs

Appointment: by Head of School. The HoS will seek to appoint members of Faculty who represent the diversity of the School.

Tenure: 3 years subject to circumstances.

SCHOOL RESEARCH ETHICS OFFICER (SREO)

Overview of Role:

Each Head of School will normally appoint at least one School Research Ethics Officer*****, with specific responsibility for the oversight of ethics review for Undergraduate (UG) and Postgraduate Taught (PGT) students.

The main function of this role will be to provide informed, independent and timely ethics review of UG and PGT projects within a culture of honesty and respect for participants, the environment and the full range of stakeholders of University research.

This role will also include provision of guidance and awareness-raising amongst colleagues and students as appropriate.

Key Responsibilities:

(a) providing final and consistent sign-off for those projects which have identified and addressed ethical issues appropriately in the proposal;

(b) discussing with Supervisor, or Supervisor and student, those projects which have not satisfactorily identified and addressed ethics issues;

(c) making final recommendation, in discussion with student's supervisor, for referral to review by the Cross-School Research Ethics Committee (C-REC) for those projects which are not 'low risk';

(d) consulting with the C-REC Chair when there are queries on ethical principles or standards for taught student research

(e)   identifying and escalating research governance and regulatory issues requiring the expertise and support of the Research Ethics, Integrity and Governance Administrator or appropriate member of the Research Ethics, Integrity and Governance team;

(f)   ensuring that policies and guidelines developed for UG and PGT students by the University and the C-REC in relation to research ethics processes are being followed in the School;

(g)   continuing to raise awareness of ethics issues and University procedures and specific requirements for ethics review for UG and PGT projects, including contributions to training and taught programmes where appropriate;

(h)   reporting, where appropriate, via the School's C-REC / Research Governance Office, on any unresolved training or development needs related to ethics issues and approval;

(i)   monitoring and reporting (with the Director of Learning and Teaching) on an annual basis on behalf of the School to the School's C-REC;

(j)   providing ad hoc informed advice and guidance to supervisors, course tutors, module leaders and UG/PGT students on research ethics applications;

(k)   ongoing contribution to the development, monitoring and review of ethics policies, procedures, and processes;

(l)   in liaison with the Research Ethics, Integrity and Governance Administrator and the Research Governance Officer, lead development and management of cross school activities and training to promote an active culture of research integrity and research ethics within and across schools, and university wide;

(m) producing and ensuring the dissemination of cross school specific guidance for faculty and students on research ethics review processes and procedures; give ad hoc support to C-REC members and other SREOs to do the same tailored for specific schools.

(n)   attendance (optional or as necessary) at C-REC meetings;

(o)   undertaking training and development activities upon taking up their role and subsequently attending a minimum of one training event annually;

(p)   liaising with the Director of Learning and Teaching and the and C-REC's Research Ethics, Integrity and Governance Administrator regarding any specific School related issues;

And, where not also a reviewer for the C-REC**:

(q)   collaboration with the School C-REC member to produce school specific guidance for faculty and students on research ethics review processes and procedures;

(r)   liaising with the School C-REC member, School based administrative and web personnel to ensure appropriate links from school websites to central ethics website, are established and maintained;

(s) liaising with the School C-REC member, the Director of Learning and Teaching and the and C-REC's Research Ethics, Integrity and Governance Administrator regarding any specific School related issues;

*In those Schools with large volumes of UG and PGT projects requiring ethics review, the Head of School may appoint at least two officers to share the role. The C-REC shall review and approve the basis on which academic schools organise the oversight of School Research Ethics Officers (SREOs) in alignment with the principles of maintaining informed, consistent, timely and independent ethics review.

Schools in which there are low volumes of ethics review of projects, may consider appointing the School's C-REC member to this role.

** Not all SREOs will act as C-REC reviewers for high risk PGT, undergraduate studies or staff and PGR applications. The terms of the SREO's reviewing duties, as specified in the letter of appointment, will be agreed by the Head of School and will be adequately reflected in the time allocated within their overall responsibilities.

Appointment: by Head of School (HoS). The HoS will seek to appoint members of Faculty who represent the diversity of the School.

Tenure: Three years, renewable for a further term.

Annex C: Terms of Reference of the University Research Ethics and Integrity Committee

Key role

To ensure that the University upholds the highest standards of rigour and integrity in all aspects of research.

  (1)   *Terms of Reference:*

  a. To keep under review and recommend University policies on issues related to:
     -ensuring integrity in all University research
     -upholding the principles of ethical research in all its forms
     -giving oversight to due diligence of non-standard research collaborators and funders
     -reviewing the outcomes of investigations into research misconduct

The above to be undertaken with a view to ensuring that the public, staff and students are protected from harm and that the reputation of the University is safeguarded.

  b. to ensure that University policy in the areas outlined above (including the *Code of Practice for Research*) is adhered to;
  c. to ensure that each Cross-School Research Ethics Committee (C-REC) is set up and operates in accordance with the requirements laid out in the University's codes and policies relating to research governance;
  d. to approve internal Schools' research governance structures and processes (including review by School Research Ethics Officers (SREOs)), and to advise, inform, and update School committees on matters of research ethics and integrity
  e. to ensure compliance with the *Concordat to Support Research Integrity* and any other significant external policies or standards relevant to University research
  f. to review anonymised accounts from any investigations into allegations of misconduct in research, offering advice and making recommendations from their outcomes
  g. to consider reports from Research and Knowledge Exchange Committee on the management of research ethics and integrity and offer advice and make recommendations;
  h. to assure the provision of appropriate training for research ethics and integrity;
  i. to consider and offer guidance on cases of uncertainty and make decisions on cases which cannot be resolved by the Animal Welfare and Ethical Review Body (AWERB) or any one of the C-RECs; to hear appeals from applicants relating to decisions of those Committees;
  j. to seek clarification from the University's external advisors or other expert bodies, as necessary, on matters of policy and practice in relation to research ethics and integrity;
  k. to receive regular reports from the C-RECs, the AWERB and the Research Governance and Quality Assurance Committee, cooperating and communicating to ensure complementary oversight and understanding of any inter-related areas.

  (2)   *Composition:* Membership

Appointed by the Vice-Chancellor:

Chair – An experienced University researcher with a significant practical understanding of research ethics and/or the application of the principles of research integrity (Term – two years renewable once)

Members appointed by the Chair to reflect the diversity of research at the University Representatives from each of the Cross-School Research Ethics Committees:
Social Sciences and Arts Cross-School Research Ethics Committee (SSARTS C-REC) – 3
Science and Technology Cross-School Research Ethics Committee (SCITEC) – 2
Brighton and Sussex Medical School Research Ethics Committee (BSMS RGEC) – 1
School Research Ethics Officers – 3
(Term – three years renewable once)

Lay members (2)

Ex-Officio members

The Chairs of the three Cross-School Research Ethics Committees (3)
The Chair or Deputy-Chair of the AWERB
The Chair of the Research Governance and Quality Assurance Committee

In attendance:

The Pro VC (Research)
Director of Research & Enterprise Services
Research Governance Officer
The Cross-School Research Ethics Committee Administrators (x 3)

(3)   *Reports to:* Senate

A quorum shall consist of a third of members of the Committee (5)
Secretarial duties – Research & Enterprise Services

Annex D – Relevant material under the Human Tissue Act (2004)

To understand the requirements to operate under one of the University's HTA licences, researchers should consult http://www.sussex.ac.uk/staff/research/governance/erp_overview/humantissue

The list is not intended as exhaustive or exclusive, but is intended to provide guidance to stakeholders in respect of a number of materials that might be considered relevant material. The HTA will review the list periodically and update it as required.

Antibodies	No
Bile	Yes
Blood	Yes
Bone marrow	Yes
Bones/skeletons	Yes
Brain	Yes
Breast milk	Yes
Breath condensates and exhaled gases	No
Buffy coat layer (interface layer between plasma and blood cells when blood is separated)	Yes
Cell lines	No
Cells that have divided in culture	No
CSF (cerebrospinal fluid)	Yes
Cystic fluid	Yes
DNA	No
Eggs (ova)*	No
Embryonic stem cells (cells derived from an embryo)	No
Embryos (outside the body)*	No
Extracted material from cells e.g. nucleic acids, cytoplasmic fractions, cell lysates, organelles, proteins, carbohydrates and lipids.	No
Faeces	Yes
Fetal tissue	Yes
Fluid from cystic lesions	Yes
Gametes*	No
Hair (from deceased person)	Yes
Hair (from living person)	No
Joint aspirates	Yes
Lysed cells	No
Mucus	Yes

Nail (from deceased person)	Yes
Nail (from living person)	No
Nasal and bronchial lavage	Yes
Non-blood, derived stem cells (i.e. derived from the body.)	Yes
Non-fetal products of conception (i.e. the amniotic fluid, umbilical cord, placenta and membranes)	Yes
Organs	Yes
Pericardial fluid	Yes
Plasma (Please note: Depending on how plasma is prepared and processed, it may contain small numbers of platelets and other blood cells. If any of these cells are present, then the plasma must be regarded as relevant material).	No
Platelets	Yes
Pleural fluid	Yes
Primary cell cultures (whole explant/biopsy present)	Yes
Pus	Yes
RNA	No
Saliva	Yes
Sebum	No
Serum	No
Skin	Yes
Sperm cells (spermatozoa)*	No
Sputum (or phlegm)	Yes
Stomach contents	Yes
Sweat	No
Teeth	Yes
Tumour tissue samples	Yes
Umbilical cord blood stem cells	Yes
Urine	Yes

https://www.hta.gov.uk/policies/relevant-material-under-human-tissue-act-2004

* While outside the definition of relevant material for the purposes of the Human Tissue Act 2004, these materials fall within the remit of the Human Fertilisation and Embryology Act 1990, and are regulated by the Human Fertilisation and Embryology Authority (HFEA).

Annex E – Responsibilities of investigators and the Chief Investigator of sponsored studies (from the UK Policy Framework for Health and Social Care) [75]

9.2. The chief investigator is the overall lead researcher for a research project[76]. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project, including:

a. satisfying themselves that the research proposal or protocol takes into account any relevant systematic reviews, other research evidence and research in progress[77], that it makes effective use of patient, service user and public involvement where appropriate and that it is scientifically sound, safe[78], ethical, legal and feasible and remains so for the duration of the research, taking account of developments while the research is ongoing;

b. satisfying themselves that the research proposal or protocol has been submitted for appropriate independent expert ('peer') review[79] and revised in light of that review;

c. satisfying themselves that, if expected or required, the proposal has been submitted for review by and obtained approval from a research ethics committee and any other relevant approval bodies;

d. satisfying themselves[80] that everyone involved in the conduct of the research is qualified by education, training[81] and experience, or otherwise competent, to discharge their roles in the project;

e. satisfying themselves that the information given to potential participants is in a suitable format and is clear and relevant to their participation in the research and, where consent is required, to their decision-making about taking part in the research[82];

f. adhering to the agreed arrangements[83] for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee);

g. adhering to the agreed arrangements[84] for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after the research has finished[85];

h. starting the research only once the sponsor has confirmed that everything is ready for it to begin;

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[75] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

[76] Outside the UK the term Coordinating Investigator or Investigator may be used.

[77] Research studies may replicate previous research, but should acknowledge the reason for doing so.

[78] i.e. that the risk of harm has been minimised as much as possible and is not expected to outweigh the benefits.

[79] For educational research, the chief investigator will be a supervisor who may provide an appropriate level of review.

[80] For multi-site projects, this may be delegated to the principal investigator at each research site.

[81] Training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards – see www.hra.nhs.uk/planning-and-improving-research/best-practice/researcher-suitability-and-training/

[82] www.hra-decisiontools.org.uk/consent

[83] see paragraph 8.10.

[84] see paragraph 8.11

[85] Funders or others may set expectations about making data and tissue available.

i. adhering to the agreed procedures and arrangements for reporting (e.g. progress reports, safety reports) and for monitoring the research, including its conduct, the participants' safety and well-being and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments; and

j. adhering to the agreed arrangements for making information about the findings of the research available, including, where appropriate[86], to participants.

9.3. Students should not normally[87] take the role of chief investigator at any level of study, as this function should be undertaken by supervisors or course leaders.

a. Relevant supervisors (or course leaders, where different) should be encouraged to develop and lead research projects that individual students at Masters level and below can contribute to at different stages. Undergraduate students should only conduct research projects in isolation that involve direct contact with patients, service users or the public in a health or social care setting if on-site supervision arrangements mitigate any risks.

b. A research culture should be fostered amongst relevant undergraduate students by encouraging an awareness of health and social care research, research ethics and public involvement, and enabling them to develop skills in research methods. Students from courses that are not primarily related to health and social care, such as business studies or IT, who wish to undertake research involving patients or service users, their data or tissue, or the public in a health or social care setting should have a co-supervisor with relevant experience that will help them understand the care context and the associated research process.

c. The contribution of students to the development, conduct and reporting of the research should be appropriately acknowledged like that of other contributors, e.g. in accordance with journal editors' authorship criteria.

9.4. Research should[88] be conducted in accordance with a research proposal or protocol – a document that describes clearly what will be done in the research. This is important so that the researchers can all understand consistently what they are supposed to do and so that the research can be properly analysed and, if necessary, reproduced. Public involvement[89] plays an important role in research design and planning. Well-planned and well-written research proposals, protocols and procedures are key to carrying out research successfully. They help avoid subsequent amendments[90], which are time-consuming and costly for the funder, the researchers and the approval bodies. However, high-quality research proposals, protocols and procedures are only effective if they are followed. Not adhering to the research proposal or protocol has the potential for adverse impact and reputational risk to all parties involved. For research participants, this compromises any informed consent given; for the researcher, it creates a scientific risk that the

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[86] www.hra.nhs.uk/planning-and-improving-research/best-practice/publication-and-dissemination-research-findings

[87] Exception is made for an experienced care practitioner or manager undertaking an educational qualification for continuing professional development or a doctoral-level study while employed by a health or social care provider or a university, or for a researcher undertaking a doctoral-level study in receipt of a fellowship.

[88] Or must, if there is a legal requirement, e.g. in the case of clinical trials of investigational medicinal products.

[89] i.e. working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research.

[90] Where research deliberately entails modifying parameters or procedures during its course (e.g. adaptive clinical trials, iterative approaches in qualitative research), amendments should be avoided by the proposal or protocol specifying the adaptation schedule and processes up front.

research data (or their credibility) may be compromised; and for sponsors, there is often a financial and resource implication, particularly where a suspension to recruitment or extensive investigation are involved.

9.5. Research proposals, protocols and procedures should be clear, comprehensive and easily accessible to the research team. Good document management and version control are essential so that, for instance, the same single version of the research proposal or protocol is being followed in the same way by everyone involved. Otherwise, the data collected could not be reliably compared, undermining the findings of the research. There is often an expectation or requirement for documents to be revised and updated during the lifespan of studies and these expectations and requirements may come from various organisations. It is important to ensure that changes to the research proposal or protocol are submitted for review, if expected or required, by a research ethics committee and any other relevant approval bodies and, if approved[91], that they are introduced uniformly across all relevant research sites.

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[91] Or if they give effect to urgent safety measures.

Annex F: SOP Healthy Volunteer Studies Administering a Substance or Other Relevant Intervention

Risk Assessment Pro-Forma

Healthy Volunteer Studies Administering a Substance or Other Relevant Intervention (Per Study)

i. **Overview of information required for approval**
ii. Submit a Risk Assessment Pro-Forma including a Delegation of Duties Log as part of the project ethics application for each study in accordance with the sections set out in the SOP Flowchart.
iii. The Risk Assessment Pro-Forma must include names of the individuals undertaking each element of the Flowchart (steps 1 – 6).
iv. The Risk Assessment Pro-Forma includes certification / accreditation requirements for any named individuals.
v. Good Clinical Practice (GCP): PI to confirm GCP training is up-to-date for anyone undertaking a task specified in the Delegation of Duties Log below.
vi. Risk Assessment Pro-Forma Sign Off – For BSMS: Risk Assessment is signed and approved by Chief Investigator and Delegator, or medically qualified PI who is a GMC registered physician with licence to practise.
vii. Risk Assessment Pro-Forma Sign Off – For Other UoS Employed Staff: Risk Assessment is signed and approved by Head of School and Chief Investigator.
viii. Any changes to the above must be notified to RGEC *and* updated approval obtained.

Purpose of Delegation of Duties Log

a) **Review:** facilitate governance review of the study via RGEC by assuring compliance with the new extension to the University's Clinical Trials insurance policy.
b) **Communicate:** how study specific processes, responsibilities and best practices will be operationally implemented by the research team.
c) **Audit:** provide clear records for the purpose of audit and evidence of good practice should an adverse event occur.

When is a study High Risk?

- Risk: if your project involves one of the following it would be regarded as <u>High Risk</u>:
  - Medicinal product
  - Discomfort or safety concerns of any kind for the participants or researchers

Study Title:	
RGEC Reference: **(For RGEC)**	
Chief Investigator and Delegator: **(NB must be a University of Sussex employee)**	
School of Chief Investigator:	

	DELEGATION OF DUTIES LOG		
Task	**Professional Role:** **Which professional or other group(s) may undertake this role? *** (e.g. GMC Registered Physician with Licence to Practise; Physician with Advanced Life Support (ALS) qualification; Registered Nurse)	**Training:** **What role specific certification/ accreditation requirements must be demonstrated?** (e.g. CPR training within a stated time period; Advanced Life Support (ALS) qualification)	**Who:** **Which named individual(s) can undertake this role?**
1) Assess eligibility and any medical risks beyond eligibility criteria			
2) Take Informed Consent			
3) Administer drug or other intervention			
(a) Calculate dose			
(b) Dispense dose			
(c) Administer dose			
4) Monitor participant (NB protocol must state how this will be done i.e. frequency; duration; type).			
5) Discharge and debriefing: provision of advice and information to take away after leaving			
6) Documentation** and archiving of risk information for each participant visit			

according to protocol.			

*The Chair or Members of RGEC can advise Investigators who are uncertain on suitable requirements.

Declaration:	I confirm that I approve this Delegation of Duties Log and confirm the individuals named above are qualified, certified and accredited according to the requirements stated on the Risk Assessment Pro-Form.
Chief Investigator and Delegator: (University of Sussex employee) Name:	
Signature:	
Head of School Name: (where applicable)	
Signature: (where applicable)	
Date:	

- **Risk Assessment Pro-Forma to be completed by Chief Investigator (BSMS) and Delegator (University of Sussex employee) or Head of School (if Chief Investigator is not based in BSMS).**
- **A copy of this Risk Assessment Pro-Forma must be placed in an electronic study master file, and a print copy must be readily available at all times in the unit where the experiment takes place.**
- **Documentation confirming who undertook each of these duties must be completed contemporaneously and retained for each participant visit in accordance with the data management and data protection policies for this study.**
- **Any planned changes in personnel must be notified in advance to RGEC and also to the Head of School if the Chief Investigator is not based in BSMS, and a revised approval signed off.**

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<u>Standard Operating Procedure:</u>

Adverse Event Management A5 Card (Per Study)

i.   Submit with the RGEC application the Standard Operating Procedure for management of adverse events.

ii.   The SOP should provide details of the procedure to be followed in the case of an adverse reaction:

    a.   immediately following ingestion of the drug

    b.   after volunteers leave the laboratory.

iii. Include as part of the Standard Operating Procedure, an A5 card for participants to present at A&E in the case of an adverse reaction, which includes PI contact details for urgent response (typically a mobile number).

iv.   The card provides at a glance the name of the drug taken, its dose and time of ingestion as well as researchers contact details.

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Today I participated in a research study at the University of Sussex. As part of the study:

I have/may have been given:_(name of drug)
_____
**The dose of (drug
name):**___(dose)_____
It was administered at: _(time and date of ingestion)
Name/Contact details of persons who administered it:
(name of
researcher)_____
PI Contact details: _____(telephone
number)_____

BSMS Research Governance and Ethics Committee (RGEC)
Adverse Event Management A5 Card 1. April 2017

Research & Enterprise Services

Falmer House

University of Sussex

http://www.sussex.ac.uk/research/governance
rgoffice@sussex.ac.uk