University of Sussex Research Ethics Policy Supporting Notes.

1. Supporting note 1: Research is defined as 'contribution to and advancement of knowledge, and a process of investigation leading to new insights, effectively shared'[1]. It is primarily demonstrated through peer reviewed publications/outputs, exhibitions, practice, research and knowledge exchange income, post graduate research (PGR) supervision, and knowledge exchange and impact. It can extend to activities such as participation in and leading research groups, work in progress series, conferences, research centres, visiting fellowships. It contributes to the Research Excellence Framework (REF) and Knowledge Exchange Framework (KEF), and to the work of scholarly associations, sector organisations and academic bodies.

   Research activity includes participatory research: Participatory research encompasses research designs, methods, and frameworks that use systematic inquiry in direct collaboration with those affected by the issue or topics being studied.

2. Supporting note 2: Research-related activities.

   Audit is a systematic and independent examination of an organisation's existing activities, systems and processes to assess compliance with regulations, policies and procedures. It measures against a standard and will identify areas of risk, inefficiency and non-compliance, and will inform delivery of improvement. Audit usually involves analysis of existing data but may include administration of an interview or questionnaire. There is no allocation of an intervention or randomisation[2].

   Service evaluation is a systematic process designed and conducted solely to define or judge a current service, to determine its effectiveness, efficiency and impact. It involves gathering and analysing data on current service delivery, outcomes and user experience, to identify areas for improvement. It does not make reference to a standard and there is no intervention or randomisation. Service evaluation usually involves analysis of existing data but may also include administration of interviews or questionnaires[3].

   Professional practice refers to the conduct and work of someone in a particular profession that may raise ethical concerns; an example would be image manipulation and content creation that utilises images from a vulnerable person or group.

   Research Impact refers to activities where the aim is to enhance the impact of research and or to evaluate the benefit that has occurred.

3. Supporting note 3: Research outside scope of this policy because it does not present any material ethical issues may include literature reviews, some laboratory-based studies, studies

[1] Research Excellence Framework (REF 2019/01 Guidance on Submissions, January 2019, revised October 2020, Annex C)

[2] Health Research Authority Defining Research Table.

utilising truly anonymised secondary data sets (Please refer to the University's Guidance on the use of Secondary Data in Research). However, there may be anomalous circumstances where such research does require ethical review and if there is uncertainty in regard to the requirement for ethical review, this should be discussed with the Research Ethics, Integrity and Governance (REIG) team to determine whether ethical review is required.

In the case of collaborative projects whereby the lead institution has a robust ethical review process and all necessary data sharing and data protection protocols are in place the researcher should retain a copy of the confirmation of a favourable ethical opinion from the lead institution and the researcher must ensure that the research is compliant with this policy. All staff and students conducting research are encouraged to review the University's Code of Practice for Research and to consider the consequences of not obtaining ethical approval should they intend to publish their results.

4. Supporting note 4: Issues that fall outside the scope of this policy include consideration of:

   - ethical issues relating to external collaborations
   - the ethics of acceptance of external funding
   - collaborations with persons or organisations that may be perceived as impacting on the impartiality of the research
   - activities conducted in countries with oppressive political regimes, a poor human rights record and/or are identified as dangerous by the Foreign and Commonwealth Office.

   These activities are outside of the remit of the School Research Ethics Officer (SREO)s, Faculty Research Ethics Committees (F- RECs) and REIG team and should instead refer to the documents below and consult with the relevant Executive Dean (or delegate) and obtain approvals where necessary.

   Freedom of Speech – Code of Practice and External Speaker Procedure
   Donations Policy
   Sanctions policy
   Export Controls policy

5. Supporting note 5: Security sensitive research is considered to be research that relates to extremism, terrorism, radicalisation and government security measures in respect of these. It may also involve research involving sensitive technologies which may require an export controls licence, and the University's Sensitive Technology Transfers and Export Controls Policy should be followed**.** Should the Foreign Influence Registration Scheme (FIRS) apply in respect of any research the applicant should obtain advice from the Governance and Compliance Manager, General Council Governance and Compliance and additional sign off may be required.

6. Supporting note 6: Undergraduate (UG) and post graduate taught (PGT) student research will be ethically reviewed first by the student's Supervisor and then by an SREO. SREOs report to the F-RECs and the F-RECs report to the University's Research Ethics and Integrity Sub-Committee which, reports to the University Research and Innovation Committee. It is expected that most UG and PGT research will be low-risk i.e. low potential for causing harm (see supporting note 7 for factors that may pose high levels of risk). However, the inexperience of UG and PGT students can

lead to the proposal of research questions, methodologies and data collection strategies that unintentionally pose significant ethical risks and/or risks to safety and wellbeing of the researcher and/or any participant. Research undertaken by UG and PGT students that follows the high-risk pathway will also be reviewed by one member of the F-REC. The SREO will offer the final opinion.

Group or module applications to the relevant SREO for UG and PGT students are acceptable, to obviate the need for individual students to submit applications. However, the research must involve be:

- Low risk
- The same or similar research topic or clearly defined range of research topics
- The same methods, activities and processes
- The same participant group
- The same method of recruitment, including receiving informed consent (where relevant)
- The same or similar interview or focus group questions (where appropriate)

The process for approval will be the same as that for high risk UG and PGT studies and involve review by a member of the F-REC; this is due to the group nature of the submission increasing the level of risk.

Staff and post graduate research will be reviewed by the relevant F-REC. For those studies deemed to be low risk, a proportionate review will be undertaken by the Chair and one member of the committee. High risk applications will receive greater scrutiny via full F-REC review.

For all reviews, specialist reviewers will be co-opted when required. These may include Health and Safety, General Counsel Governance and Compliance, Insurance Manager, IT Services.

UG and PGT projects involving animals will first be reviewed by the student's Supervisor before submission to and approval by the AWERB and/or Applications Review Group.

7. Supporting note 7: Factors that may pose high levels of risk include:

- A physical risk to participants and/or the researcher e.g. collection of human materials, administration of food substances
- Potential to cause psychological stress, distress, anxiety, humiliation or other negative consequences
- Involvement of participants who could be considered vulnerable or could feel coerced or obliged to take part or disadvantaged by not taking part
- Deception and/or participation without consent
- Potential to identify research participants in publications or outputs
- Studies that may lead to disclosures from the participant that raise ethical or moral dilemmas, involvement in illegal actions or risk of harm to themselves or others
- The collection of personal, special category data

- The UK GDPR singles out some types of personal data as likely to be more sensitive, and gives them extra protection[3]:

    - personal data revealing racial or ethnic origin
    - personal data revealing political opinions
    - personal data revealing religious or philosophical beliefs
    - personal data revealing trade union membership
    - genetic data.
    - biometric data (where used for identification purposes)
    - data concerning health
    - data concerning a person's sex life
    - data concerning a person's sexual orientation

- Research into sexual activity, relationships and/or sexual identity
- Research on trans and/ or gender identity, and/ or gender reassignment
- Research exploring or involving illegal activities, requiring access to or handling of materials related to illegal activities and/or could lead to the disclosure of information that could facilitate illegal activities.

On a case-by-case basis there may be reasons why a project might technically appear high risk but a case can be made for it to be considered low risk.

8. Supporting note 8: The University's current on-line ethics management system is Sussex Direct until implementation of Infonetica.

9. Supporting note 9: The Health and Social Care Sponsorship Sub-Committee will review applications intended for submission to:

    - Health Research Authority
    - NHS Research Ethics Committee
    - His Majesty's Prison and Probation Services (HMPPS) National Research Committee
    - Ministry of Defence Research Ethics Committee (MOD REC)

    In the case of the HRA and NHS REC, applications will first be reviewed by the Pre- Sponsorship Review Panel.

10. Supporting note 10: Specialist governance review for mass data (the automated collection of a data set with >1000 data subjects) studies include:

    - Assistant Director of IT Services, Strategy and Architecture
    - Head of Information Management and Compliance
    - Senior Legal Counsel

[3] UK General Data Protection Regulation.

- The Insurance Manager

11. Supporting note 11: In collaborative research, ethical review at Sussex will be required if Sussex staff or students are directly involved in recruitment and/or data collection, and appropriate collaboration and data sharing agreements are not in place.

    Ethical review would also be required if the lead institution or organisation does not have comparable ethical review standards.

    In the latter scenario, the REIG team should be consulted to determine on an individual basis whether the University will undertake the review and whether it will be for the whole project or the part to be undertaken by University staff and/or students.

    External research projects that seek recruitment of Sussex staff or students would be expected to have received a favourable ethical opinion from a comparable ethical review body, and a copy of the opinion to be provided to any person asked to act as gatekeeper at the University.

12. Supporting note 12: Research that is considered particularly challenging for UG or PGT level study, and will require additional sign off by the Executive Dean or delegate in advance of seeking ethical approval, includes:

    - Research that relates to extremism, terrorism, radicalisation and government security measure in respect of these.
    - National security sensitive research such as that involving weapons of mass destruction or dual use technologies.

    Research that may require additional sign off at the discretion of the Executive Dean includes;

    - Research into illegal activities that require access to or handling of materials related to illegal activities and/or could lead to the disclosure of information that could facilitate illegal activities.
    - Research with the potential to cause psychological trauma to the researcher or participant because appropriate safeguards are not in place e.g. Supervisor experience of the research area, suitable safeguarding route, adequate researcher experience in responding to and supporting distressed persons.
    - Lived experience where the topic may be triggering to the student or the participant.
    - Interviewing victims of sexual violence.
    - Research into sexual activity, relationships and/or sexual identity without appropriate safeguards in place.
    - Research involving pornography or distressing videos/images.

    Topics in the above contexts may include:

    - ‘Race’ or ethnicity
    - Political, religious, spiritual, or other beliefs

- Physical or mental health conditions
- Sexuality and/or gender identity
- Abuse (child, adult)
- Past trauma
- Nudity and the body
- Criminal activities
- Political asylum
- Conflict situations and personal violence/exploitation
- Hate crime.

Researchers should consider that there are potential risks relating to such research that may arise prior to data collection. Careful consideration should be given at the start of the research journey, to ensure that potential risks to both participants and researchers are mitigated, and to support the safety and wellbeing of all those involved in the project.

13. Supporting note 13: When audit, service evaluation or professional practice activities involve activities of high risk, ethical scrutiny of the project must be undertaken.

    For low risk research-related activity projects involving either staff or PGRs, ethical approval is not required. However, consideration should be given to the intentions of the work, for example, publication and any funder or external organisational requirements e.g., School or local authority. This may determine whether ethical review is needed.

    For low risk UG and PGT work, ethical approval for research-related activity projects involving human or animal participation is still required, unless the project is taking place within the NHS and the following criteria are fulfilled:

    - Confirmation is provided that the project is not research using: Is my study research? (hra-decisiontools.org.uk)
    - Confirmation of clinical governance approval from the relevant Trust.

    For research impact see supporting note 14.

14. Supporting note 14: Research impact.

    For engagement and impact activities i.e. those where the aim is to enhance the impact of research and or to evaluate the benefit that has occurred, ethical approval for impact activities is not routinely required. However, there are circumstances where it will be required.

    Where possible, plans for engagement and impact activities, and for collecting and recording the evidence of impact, should be included in an initial research project plan/proposal and taken through ethical review as part of that broader project plan.

    It is recognised that impact opportunities will often emerge during or after the underpinning research is conducted and will not necessarily be predictable in advance. Where a new impact opportunity arises, individuals should consider it with reference to the requirements of ethical review.

Ethical approval must be sought if impact activities or evaluation include the following:

Impact activity risks:

- There is a physical risk to human or animal participants, the researcher and/or the natural environment.
- There is active discussion of topics with the potential to cause stress, distress, anxiety, humiliation or other negative emotions, especially if the sensitivity or potential to generate such reactions will not be obvious to the participants in advance.
- There is involvement of participants who could be considered vulnerable or could feel coerced or obliged to take part, or disadvantaged by not taking part.
- The project involves deception and/or participation without consent.
- There are financial inducements over and above expenses and reimbursement for time.

Impact evaluation risks:

- There is access or collection of confidential, personal or sensitive information that may be used outside of the sole purpose of evaluating the impact of a research project, for example to inform wider research enquiry.
- There may be disclosure of confidential information beyond the initial consent given if a participant discloses information indicating they may be at risk of harm to themselves or others. This disclosure is necessary for safeguarding purposes to ensure appropriate action can be taken.
- There is an intention or likelihood that you may wish to use data for future research, or to present your findings externally to the University e.g., publications, conferences, websites. The exception to this is presentation for formal research assessment exercises such as the REF, as risks are managed through the specific consent and confidentiality processes in place for REF impact case studies both at the University and Research England.

Individuals involved in engagement and impact activities should reflect on the nature of these activities and consider whether they fall within the scope of these requirements.

If a particular activity intended to generate impact and/or to gather evidence of impact raises an ethical concern that have not been recorded and addressed through an ethical review process, or for which the planned mitigation strategies prove ineffective, this should be reported to the Research Ethics, Integrity and Governance team for advice at the earliest opportunity, and researchers are strongly advised to avoid undertaking or progressing the activity until advice has been given.

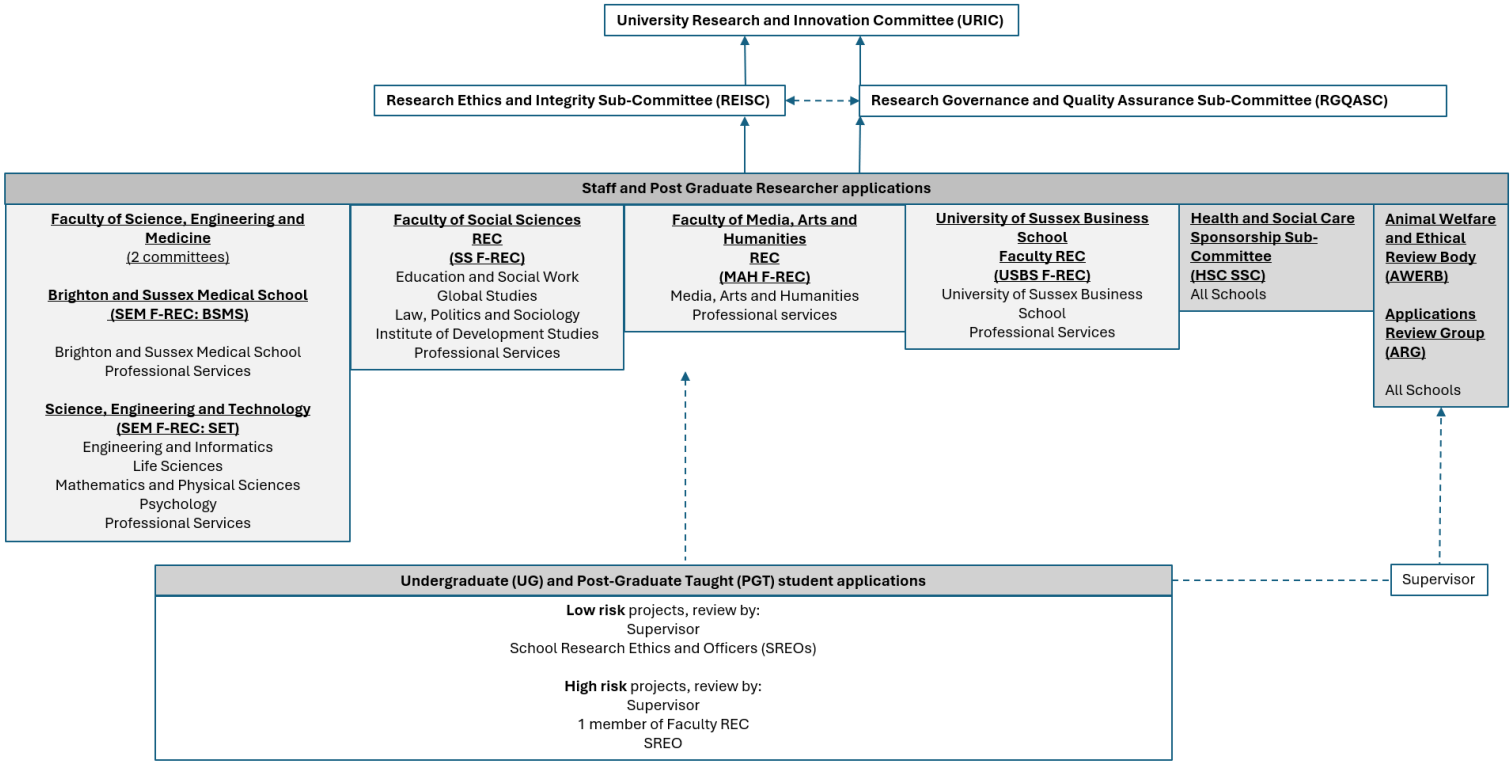
For avoidance of doubt, researchers are not responsible for the use of their research by others, or for negative impacts, where they have not encouraged, directed, or participated in such use, or left the research open to such use by any negligence of their responsibilities. However, researchers are encouraged to consider, at the point of their initial project planning and throughout their research-related activities, the potential uses, including any misuse or negative impact, by any parties of their research, and to seek advice where appropriate to reduce the potential for misuse and negative impact from their work.

15. Supporting note 15: In the case of both staff and student research, changes to a research project must be notified to the F-REC or SREO as relevant, and must be granted a favourable opinion prior to taking effect. Examples include changes to:

- The end date or duration of the project
- A change to recruitment materials
- A change to the design of the research or methods used
- A change in location
- A change in the management of data
- A change in sample size and/or exclusion/inclusion criteria

If there are no material ethical issues arising from the amendment, the amendment will be assessed by the F-REC Chair or SREO only; otherwise it will be reviewed via the proportionate system of review.

Supporting Diagram 1: University of Sussex Ethics and Governance Committee structure



REC: Research Ethics Committee