UWE Bristol Handbook of Research Ethics

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1 Research Ethics Introduction

1.1 Introduction

This document sets out the policy, procedures and guidance for research ethics review at UWE, Bristol. The University embraces and encourages the wide range of research activity with which staff and students engage. Research integrity is at the core of high-quality research. All research at UWE should adhere to the highest ethical standards and any research which has the potential to raise significant ethical concerns must be submitted for independent ethical review. In any research involving people, their data or tissue, their dignity, rights, safety and wellbeing must be a significant consideration. Similarly, for any research involving animals, their welfare or the environment, ethics are underpinning concerns. The University is required by the Concordat to Support Research Integrity (Universities UK, 2019) to have appropriate procedures for ensuring the integrity of research. Staff and students are also expected to carry out research in accordance with the UWE Bristol *Code of Good Research Conduct* (2022).

For staff and postgraduate research (PGR) students, the University approach is based on the ethical scrutiny of individual research projects by Faculty Research Ethics Committees (FRECs) which have been established in each of the Faculties of the University. These operate to standard terms of reference, composition and procedures as described below.

For undergraduate (UG) and postgraduate taught (PGT)/Masters students, responsibility for ethical review has been given to supervisors, except in the case of those projects deemed high risk, which are also reviewed by FRECs. The expectation is that supervisors will work with UG and PGT students in most instances to identify appropriate low risk research projects, and that such high risk UG/PGT student applications to FRECs will be exceptional. See Section 2.5 below for more details.

It is the researcher's responsibility (and the Supervisor's in the case of students) to identify the potential risks their research may pose for participants and to address these in the ethics application (and in supervision for students).

These procedures apply to all staff (including Emeritus or visiting colleagues) and students conducting or contributing to research which take place within the University or on projects managed by the University. They also apply to individuals who are not members of the University but who are engaged in such research activities involving University premises, facilities, students or staff. UWE staff collaborating with or on secondment to other institutions should have a favourable ethical opinion from UWE or another appropriately constituted REC. A favourable ethical opinion from another properly constituted Research Ethics Committee (REC) can then be ratified by UWE (see Section 2.3 below).

For research involving animals or animal by-products, all research is considered by the Animal Welfare and Ethics Sub-Committee (AWESC). AWESC detailed requirements are covered in separate

policy and guidance, and are not covered in detail in this handbook (contact researchgovernance@uwe.ac.uk for further guidance).

1.2 Why are research ethics important?

Research ethics are important because it is very possible for research to cause significant harm as well as bring many benefits to people, animals and/or the environment. The recognition of the need for guidelines dealing with human subjects in research emerged following the Nuremberg trials, where the medical experimentation abuses of Nazi doctors came to public attention. This led to the creation of the Nuremberg Code in 1945, the first legal attempt to deal with ethical issues of modern research. As biomedical research expanded the international need for a more specific code of ethics was formulated in the 1964 Declaration of Helsinki. Unfortunately, such codes of ethics did not prevent ongoing instances of unethical research practice. One notorious example was the Tuskegee Syphilis Study, exposed in 1972 as a 30-year US government supported study in which 300 African-American men were left untreated after effective antibiotics were available. In response to other ethical abuses in the UK, research ethics committees have been established both in the NHS and in universities to seek to ensure that research done in or by UK institutions adheres to the highest ethical standards and participants are not exposed to any unnecessary risks. Ethical review by peers on research ethics committees is important because this enables researchers to benefit from the considerable ethics expertise of committee members, and to provide assurance to the University, research participants, funders, publishers and wider publics that research has been independently evaluated.

1.3 What are the key principles in research ethics?

The use of principles to underpin good ethical research practice has become well-established and agreed, although there are a variety of different statements of principles in use which vary somewhat in wording. The most widely used principles for research ethics review are the 'Belmont Principles' widely disseminated by Beauchamp and Childress (2019):

- **Respect for persons (and their autonomy)**
  Participation in research should be voluntary
  Potential participants should be given enough information to make an informed choice as to whether they want to participate in the research, and to have the right to withdraw without penalty.
- **Beneficence**
  Benefits from the research should outweigh any risks
  Overall, the benefits of the research (either to the participant or more generally to society) should outweigh the risks.
- **Non-maleficence**
  Risks to individuals should be minimised
  Research should be designed and conducted in a way that minimises any potential harms. Some risks are unavoidable, but they should only be accepted if there is no other option and researchers should aim to mitigate them.
- **Justice**
  Benefits and risks should be equally shared
  There are a number of ways in which justice should be considered. For example, within studies, the distribution of risks and benefits should be equitable. Within populations, research participants should stand a reasonable chance of benefiting from the outcome of the research.

More recently, it has been recognised that research ethics should also consider principles not directly connected to human participants. For example, research ethics must consider risks or harms to the environment as well as to human participants and animals.

1.4 Types of research requiring ethical review

Ethical scrutiny of all research involving **human participants, their tissue or their data** is formally required by the University, except in in the specific circumstances as detailed in section 1.3 below. Externally funded research must meet the standards expected of funding agencies. Evaluation studies involving human participants also require ethical review, except in the case of customer satisfaction surveys or module evaluations which do not collect any personal data.

Research using **human tissue** always requires ethical review. For guidance on this see Human tissue research and teaching at UWE Bristol.

Research which does not involve human participants or animals but which might have a negative environmental or societal impact requires ethical review.

Research involving politically and/or culturally sensitive funding sources or partners should be submitted for ethical review. The University has agreed only one absolute prohibition on research funding:

> The University's policy is that it does not knowingly accept any monies from sources funded by the tobacco industry.

Otherwise, it is for the researcher to make the case, in advance, for the ethicality of seeking funding from sensitive sources, for example, by demonstrating that the proposed research will lead to the funder operating in a more socially or environmentally beneficial manner.

Research which has potential for **dual use** where significant harm could occur should also be submitted for ethical review. Dual use is a term that is applied to the tangible and intangible features of a technology that enable it to be applied to both hostile and peaceful ends with no, or only minor, modifications.

Security-sensitive research must be submitted to the University Research Ethics Sub-Committee (RESC) for ethical review (see section 10 below).

Secondary data analysis requires ethical review except in the specific circumstances as detailed in section 1.3 below (see also section 7 below on secondary analysis).

Social media data analysis, even if anonymised and in the public domain, retains a risk the data could be used to re-identify individuals, thus ethical review will be required (see section 8).

Animal research: All research involving animals or animal by-products requires ethical review in line with AWESC policy and procedures. AWESC has procedures separate from RESC, due to the nature of its business. The following detailed requirements/guidance relate specifically to RESC and FRECs.

1.5 Types of research not requiring ethical review

The following types of research do not usually require ethical review:

Research involving **information freely available in the public domain**, for example, reports and minutes of government departments, parliamentary committees, public bodies and inquiries,

published biographies and newspaper accounts. Where individuals are named in such data, GDPR data protection requirements still apply even if ethical review is not required.

Research involving **completely anonymised data that exist in the public domain** where appropriate safeguards are already in place and permissions have been obtained, for example from the Office for National Statistics or the UK Data Archive. However, if anonymous data sets are being linked in a way that might allow individuals to be re-identified, then ethical review will be required.

Evidence synthesis (including system reviews, realist reviews, meta-ethnography) of published literature.

If in doubt as to whether proposed research requires ethical review, please consult the appropriate RESC or FREC chair via researchethics@uwe.ac.uk.

2 University Research Ethics Sub-Committee and Faculty Research Ethics Committees

The University RESC reports via the University RKEC to Academic Board which is chaired by the Vice-Chancellor of the University.

Each Faculty has a FREC, which is a sub-committee of the Faculty RKEC, reporting to Faculty Board.

The terms of reference of RESC and FRECs are available at the Committees and groups web pages.

Collectively the RESC and FRECs are referred to as University RECs.

2.1 Composition and membership

The University RECs are constituted to ensure the competent review and evaluation of all ethical aspects of the research projects they receive. The University will expect the membership of committees to be inclusive, recognising the diversity of the research community in terms of the gender, age, ethnicity and background of members.

An appointed member must be prepared to have published his/her full name, profession and affiliation. When making appointments, potential conflicts of interest should be declared. There should be transparency with regard to such interests, and they should be recorded and published with the above personal details, and updated as appropriate. The Chair will make a decision as to whether a conflict of interest is relevant based on the matter at hand.

An appointed member is expected to maintain confidentiality regarding applications, meeting deliberations, information on research participants, and related matters.

For University staff, the time required for undertaking such service and the necessary training must be protected. This is part of collegiate professional activity, and it must be recognised as a fundamentally important activity on behalf of the University, without which research could not take place. In line with its commitment to the *Concordat to Support Research Integrity*, the University will ensure appropriate resourcing of FREC and RESC membership, including the time of members to properly discharge their duties as scrutineers and as part of collegial decision making.

A Committee member is normally required to attend in full at least two-thirds of all scheduled Committee meetings in each academic year. Attendance at scheduled meetings should be of sufficient frequency to ensure a member's effective contribution to the work of the Committee. Committee

members will normally be required to scrutinise at least two-thirds of the applications they are asked to review in each academic year.

The roles and responsibilities of REC members are set out in Annex 2.

2.2 Training

University REC members will need initial and continuing education and training regarding research ethics and governance. As a condition of appointment, a member should agree to take part in initial and continuing education appropriate to his or her role as a REC member. It is particularly important that Chairs and Deputy Chairs are fully aware of, and up to date with, ethical considerations and are therefore expected to undergo any additional training identified for them.

All academic staff are expected to complete the mandatory online research ethics training to ensure that they have the basic knowledge and understanding of research ethics to conduct research ethically and/or to appropriately supervise student research.

2.3 Basis of a favourable opinion by University RECs

A primary task of the RECs lies in the ethical review of research proposals and their supporting documents, with special attention given to the nature of any intervention and its safety and protection for participants and researchers, to the informed consent process, documentation, and to the suitability and feasibility of the proposal.

A decision by a REC to give a favourable opinion to a research project does not imply an expert assessment of all possible ethical issues or of all possible dangers or risks involved, nor does it detract in any way from the ultimate responsibility which researchers must themselves have for all research which they carry out and for its effects on human participants. Other University reviews and/or approvals may be needed, for example from Research Governance, Health and Safety, Contracts, Data Protection or Corporate Governance. The RECs address themselves to ethical matters and are dependent upon information supplied by the researcher. This information is expected to be properly researched, full, truthful and accurate. **Failure to follow the University's policy and procedures on ethical review of research may be regarded as research misconduct**.

In order to give a favourable opinion on proposed research, the REC will need to be adequately reassured about such issues as:

- the design and conduct of the study
- the recruitment of research participants (or the observation of people if not directly recruited)
- the informed consent process
- the care and protection of research participants and others affected by the research
- the right of research participants to withdraw
- the protection of research participants' confidentiality
- research data management plans and data security
- research data sharing arrangements or data disposal, including General Data Protection Regulation (GDPR) requirements
- storage arrangements for human tissue (relevant material under the HTA or coming under the provisions of the HFEA) or other human tissue derived materials (acellular materials)

- For student research, that the proposed research is appropriate for the level of study of the student and that there is appropriate supervision in place (students, including postgraduate research (PGR) students, are researchers in training)
-
- any community considerations both within and externally to the University

Annex 2 to this Handbook gives FREC Chairs' practical top tips on getting your ethics application approved quickly.

A decision by a REC to give a favourable ethical opinion on a research project does not constitute a precedent and each application will be judged on its own merits and in the light of present circumstances.

A decision to change the University's policies or procedures for ethical review of research does not imply that previous policies or procedures were inappropriate and any such changes do not invalidate previous favourable ethical opinions that have been given.

Research projects should generally only be reviewed by a single REC, so if UWE researchers have an NHS or another UK university REC favourable opinion, they will usually only need UWE REC ratification (other than in exceptional circumstances, such as a funder requiring review for their own processes). For ratification the researcher will need to provide a copy of the original application for ethics review (including protocol and any patient facing documents) which was made to the other institution, and a copy of the favourable opinion letter, to the relevant UWE REC. Ratification can then usually be done by Chair's Action without any need for additional scrutiny. In the case of non-UK institutions, such requests should be dealt with on a case-by-case basis by the Chair of the relevant committee. Where a request for ratification does not provide sufficient supporting information a full application for ethical review will be required. The research data collection phase cannot begin until ratification has been granted.

2.4 Staff and PGR (doctoral) student ethics applications

Staff and PGR (doctoral) student applications to RECs will be allocated to two REC reviewers. Reviewer recommendations will be passed to the REC chair who will make the final decision. On occasion, for example retrospective applications to RESC, all RESC members will be asked to review and give a recommendation. This may be either at a scheduled meeting or virtually between meetings. Decisions will be either a favourable opinion to proceed, conditional favourable opinion, revise and resubmit or reject.

University RECs shall retain all relevant records for a period of at least six years or longer if required for legal, regulatory or insurance purposes. Records shall be made available upon request to appropriate regulatory authorities.

The RECs should always be able to demonstrate that they have acted responsibly in reaching a particular decision. When a REC rejects a research proposal, the reasons for that decision shall be made available to the applicant and, where appropriate, opportunities for resubmission provided. Where given a favourable opinion, the basis for that decision should be recorded.

The RECs shall consider valid applications in a timely manner. A decision should be reached and communicated to the applicant, wherever possible, within six working weeks of the submission of a valid application. Applicants should submit applications in good time, at least six working weeks before the research activities for which approval is necessary are proposed to commence. Researchers should

allow sufficient time within their plans for any conditions to be responded to prior to commencement of data collection.

Where significant amendments are made to the research protocol following REC approval, the researcher is responsible for notifying the REC of these for review. Amendments submitted once ethical scrutiny has been completed shall normally be dealt with through Chair's Action.

Any adverse events which occur as a result of the research should be notified in a timely way to the REC which approved the research.

Where the research is terminated prematurely, a report shall be provided to the relevant committee within 14 days, indicating the reasons for early termination.

Detailed information about how to apply is at Annex 1.

2.5 Undergraduate and PGT (Masters) student applications

Undergraduate (UG) and PGT (Masters) research projects carried out as part of taught modules including dissertations require ethical review in the first instance by the UWE supervisor. All student research must be supervised and the supervisor is responsible for the conduct of the research. A formal project proposal is needed which clearly discusses and addresses any ethical issues in order for it to be reviewed and approved. The supervisor and student should retain a copy of the project proposal and the favourable ethics opinion, and approval of any amendments, and the confirmation letter or email should also be included as an appendix to the dissertation.

The University approach to student research is proportionate to the level of study and the potential risks of doing the research. The level of risk will usually be determined by completing the University's online Student Ethical Review Record for Taught Programmes. Supervisors may give a favourable opinion to proceed to any project deemed low risk. If a project appears high risk on initial assessment, the supervisor should work with the student to seek to change the proposal to mitigate the risks in order that it can become low risk. In exceptional circumstances where the benefits of the proposed research may outweigh the risks, the supervisor may support the student to submit a full application to the relevant FREC.

In some cases, programmes may require UG or PGT/Masters students to complete a full ethics application form for educational or professional reasons even if the research is deemed low risk. This local variation in practice is appropriate, but in this case the form should not be submitted to the FREC.

Apprenticeship programmes

Apprenticeship degree programmes are relatively new and do not usually include a research module. If a research module is included, or any research conducted for an assignment on another module, then any such research will be covered by the usual UWE procedures.

In apprenticeship programmes 20% of the learning will be off-the-job and mainly provided by the University through taught modules but 80% of the learning will be on the job. This may include service evaluation which will be supervised by a workplace supervisor rather than a UWE tutor. In some instances, such service evaluation may be similar to research and raise ethical issues which should be addressed through the employing organisation's own research governance and ethics systems. For some employers this may be well developed, as in the case of the NHS; other employers may or may not have such systems. As it will not be module-based and there will be no

UWE supervisor involved, it will not be appropriate to take such workplace-based service evaluations through the formal UWE ethical review process. However, UWE will want to support the student in understanding and applying good ethical practice; for example, UWE tutors can signpost workplace supervisors and apprentices to appropriate resources, including publicly available research ethics guidance on the UWE website and elsewhere, such as the NHS Health Research Authority (HRA). Any ethics documentation used in apprenticeship workplace-based service evaluations such as consent forms and participant information sheets should be clearly identified with the employer's logo and details and not UWE's.

In some cases, a workplace-based service evaluation may form part of the portfolio of evidence presented at the end of the degree programme as part of the End Point Assessment. In this case it would be expected that a reflective note would be included in the portfolio making clear how any such evaluation involving human participants or their data was conducted to a high ethical standard and in line with the employer's research governance and ethics requirements.

2.6 Research in the NHS and social care

When research is being carried out in the NHS with patients, their data or tissue, application must be made to an NHS REC via the Health Research Authority's Integrated Research Application System. Staff and doctoral student research applications are accepted for NHS REC review, and some Masters level applications may be eligible (Masters students need to complete the Student Research Toolkit to check eligibility). Students working at undergraduate level are no longer accepted for REC review.

Advice should be sought from the UWE Research Ethics team before applying, and the University will need to agree to be the research Sponsor. Once the application has been prepared (and approved by the supervisor in the case of student research), notification of the intention to submit should be sent to researchethics@uwe.ac.uk. The application will need to be checked before a sponsorship letter is prepared if UWE is to be the Sponsor. For student applications, the HRA usually expects supervisors to attend the NHS REC meeting where a student application is being discussed.

Once the application has been reviewed and given a favourable opinion by an NHS REC a copy of the final application and favourable opinion letter should be sent to the FREC where the Chair will formally ratify the NHS REC decision.

It is important to note two specific points about research in the NHS. First, to be aware that University and NHS definitions of research may differ, and some research with NHS staff and/or evaluation and audit studies may not require NHS REC review but will still require UWE ethical review. Second, all University projects taking place in the NHS may require NHS Research & Development (R&D) approval even if they do not require NHS REC review. You should approach the relevant NHS R&D department at an early stage in the planning of the research project for advice about their approval process. Normally an application for R&D approval using IRAS may be required.

The HRA also covers some social care research, in particular social care studies funded by the Department of Health and some social care research that involves people lacking mental capacity see here. All research involving human tissue which is covered by the Human Tissue Act taking place at UWE requires HRA approval. See the HRA website for details of which studies are appropriate to submit to it. If appropriate, the UWE process is the same as for NHS REC studies.

It is important to note that there are strict laws and rules governing how identifiable patient data can be used. Guidance in relation to this issue is provided at **Annex 3** and this must be complied with.

2.7 Applying for retrospective ethical review

It is not expected that applications will be received for retrospective review, save in exceptional circumstances. Where an exceptional circumstance exists, a two-stage process is followed:

Step 1: The applicant must satisfy the RESC that there are exceptional circumstances for their failure before starting their research to obtain a favourable ethical opinion;

Step 2: The full RESC on a majority vote must agree that the application could be approved without conditions. Given that a favourable opinion is often conditional, the Committee agreed that in such cases, provided general ethical principles have been followed, and the conditions would have constituted points for clarification or minor issues such as corrections of typos, then the research could be considered as having been capable of a favourable opinion.

Applications must therefore be made to RESC with a full explanation of the reasons why ethical review was not sought and a favourable opinion obtained before the research was carried out. Any supporting evidence must also be provided. The full RESC will consider the reasons and decide whether it considers the circumstances to be exceptional. A record will be kept of decided cases by the RESC. If the reasons are considered exceptional, and therefore the application can proceed to the second stage of the process, the full RESC will vote on whether the application as submitted to RESC could have been given a favourable opinion without conditions. If both conditions are satisfied, the RESC may exercise its discretion to grant a favourable opinion for the research. When the full committee agrees that the conditions for a favourable opinion can be met this decision may be approved by email.

For all applicants:

At Stage 1, a case must be made why the circumstances are genuinely exceptional. The procedure is not a 'catch all' for those who forgot, or failed to properly understand, their ethical obligations. This first Stage is therefore a necessary pre-requisite for any consideration of the substantive application.

If the Stage 1 justification is accepted by the Committee, then the Committee will move on to assess whether it would have given an unconditional favourable opinion. If so, then a favourable opinion may be granted. If, however, conditions would have been given, then it cannot retrospectively be given, as, de facto, research would have taken place which the Committee considered did not meet acceptable standards. This would then be rejected, and the matter would need to be referred for appropriate management action, including, potentially, a referral to the Research Misconduct Procedures (as the research would have taken place without the necessary ethical review). In this regard, the Committee could and should highlight within that any immediate ethical concerns particularly in relation to any ongoing concerns regarding the welfare of human participants.

The decision as to whether there needs to be a full Committee discussion of a case, or whether the matter can be dealt with by Committee correspondence, will rest with the Chair.

There may be an 'innocent party' involved. Students will generally be considered to be an 'innocent party', as they are under Supervision and the UWE Project Manager is the DOS/Supervisor. However,

this will not in every case apply, for example if the student has failed to act on the instruction of the supervisor. As an exemplar, if there is ethical review, but the student has then done something other than or additional to what is covered, without the Supervisor's knowledge or against their advice, then the student is not clearly an entirely 'innocent party'. Equally, external collaborators would usually be entitled to rely upon the UWE collaborator having obtained ethical review where that had been agreed, but it might reasonably be expected that there would be some evidence that they had taken steps to agree who was responsible for the ethical review. It may be necessary to obtain further detail on this point to enable the Committee to take a decision about whether the matter should pass to the next stage for review of the application. Such issues can be tricky to unpick, and the Research Governance Manager will advise the Committee as appropriate. Where, and only where, there is an 'innocent party' who may be unfairly disadvantaged by a refusal to grant a retrospective favourable opinion, the proposed operation of the procedure also allows for the following:

Even where there is no adequate case made for exceptional circumstances (such as where the Supervisor has simply failed to ensure that the application was made), where there is an 'innocent party', the retrospective application can proceed to Stage 2.

If it is not clear that the application would have been granted an unconditional favourable opinion, then it can be agreed, in line with Stage 2 of the Policy. This does not, however, prevent the Committee from making a referral for management action, including to the appropriate Research Misconduct Procedures (e.g. a referral of the Supervisor whose failure it was that the application was not made properly in advance) or Conduct Procedures (in relation to non-research activities) or other appropriate management action. But is does mean the innocent party, where the research, as conducted, was entirely ethical, is not unfairly penalised.

If it is clear that a conditional opinion only would have been granted, the application will be rejected. The provisions relating to the 'innocent party' are intended to permit an application to proceed to step 2 even if there is no good exceptional circumstances case. It is never intended that research which has taken place and which the Committee considers not to meet appropriate ethical standards should receive a retrospective favourable opinion.

If it is not clear whether the research would have been approved unconditionally, for example if the application is not well put together, the Committee may choose to iterate to establish the facts. If, following iteration about what actually took place in the research, the Committee is satisfied, a favourable opinion can be given; if not, the application will be rejected.

2.8 Ethical review appeal process

Grounds for making an appeal

Appeals against final decisions of any UWE REC will be permitted on the following procedural grounds:

- That there were procedural irregularities within the review process that could have influenced the outcome of the application; or
- That there is evidence of inadequate review, prejudice, bias or adverse review of methodology beyond that which relates to ethics within the review process which demonstrably influenced the decision.

Process for making an appeal

- In the first instance the matter should be raised informally with the Chair of the REC which scrutinised the application by email to researchethics@uwe.ac.uk.
- If the matter cannot be resolved informally by the relevant ethics committee, the matter should be raised formally with the Chair of RESC unless the scrutinising committee was RESC, in which case the matter should be raised formally with the Chair of RKEC.
- All appeals must provide the name of the applicant on the original ethics application, the Director of Studies or the Supervisor's name where the original ethical review application was made by a student, and the ethics committee application number. The relevant grounds and supporting information should be sent to researchethics@uwe.ac.uk, noting 'Appeal' in the email subject line.
- Appeals must be made within ten working days of the applicant being notified of the final ethical decision, or otherwise becoming aware of the alleged procedural irregularity.

Process for investigating an appeal

- Most cases will be able to be resolved by the relevant committee Chair. In complex cases the Chair may convene a small panel (usually three REC members and/or members co-opted for their expertise from within or outside UWE) to assist them in reaching a decision. Members must not have a close association with the individual making the Appeal, or with the project that is the subject of the appeal. The Officer for the Panel will normally be drawn from within RBI Research Governance and Ethics Team.
- The Chair (with the assistance of the Panel where the Chair considers it necessary) will investigate the appeal, and normally complete its work within 20 working days of its receipt.
- The deliberations of the Chair and the Panel will be confidential. However, the Chair/Panel is at liberty to consult, in confidence, anyone it deems appropriate to conduct its work. The Chair/Panel may also request any other evidence it deems necessary including a request to interview any UWE ethics committee member.
- The Chair and/or the Panel will confine their investigation to the matter that is raised as the subject of the appeal or the complaint.
- The outcome of the appeal will be communicated in writing, usually within thirty working days of receipt of the appeal.
- If the applicant remains unsatisfied with the Chair's decision, the appeal will be referred to the Chair of the RESC who will make a decision. If the applicant remains unsatisfied (or if the appeal is against RESC), the appeal will be referred to the Chair of RKEC. The RKEC Chair's decision cannot be further appealed.
- Appeals and their outcomes will be reported to RESC and the relevant FREC committees

2.9 Legal issues

It is the researcher's responsibility to ensure that the research conforms to relevant legal or regulatory requirements and to seek appropriate guidance through the University Research Governance team (researchgovernance@uwe.ac.uk) if needed. University RECs have a responsibility to take into account legal matters directly related to the ethical consideration of the way in which research is to be conducted, as research which does not comply with legal and regulatory requirements cannot be considered to be ethical. It is not the responsibility of the REC to give advice on wider legal issues which might affect whether and how the research should be permitted to go ahead or to approve that

the research is legal, but it may request additional information on legal aspects of the research to assist in its deliberation if needed.

2.10 Monitoring, auditing and reporting

The RESC and FRECs recognise that the definition and perceived significance of ethical problems may be subject to change and difference of opinion. In this light, the RESC will conduct an annual review of its work reporting annually to RKEC on the management of the Committees via an annual assurance report, indicating in particular any suggested or agreed change in policy or procedures. The RESC will also report on any outstanding or anticipated difficulties. Each FREC will provide a report to the RESC for these purposes. A list of all submissions and the decision taken in respect of them together with any major issues arising and a record of applications considered outside formal meetings will be required as part of the annual report. Each FREC annual report will also be presented to the appropriate Faculty RKEC for information.

The RESC will carry out an annual audit on selected aspects of RESC's and FRECs' work, including reviewing procedures, record keeping of the RECs, reviewing a sample of ethics applications and monitoring and auditing of research activities to ensure compliance with the decisions of the RECs. RESC will present an Annual Audit Report to RKEC.

2.11 RESC review process

In the event that a FREC finds itself unable to make a decision regarding a particular research proposal, it may, at any time, forward the research proposal to the RESC for its consideration. This could be due, for example, to the complexity of the proposed research, or due to a split decision within the FREC. The FREC can refer cases to the RESC that require advice or opinion. Referral to the RESC for a review will be in exceptional circumstances only. The RESC will not normally challenge FREC decisions. Once a FREC has declined to give a favourable opinion on the application and opportunities for resubmission have been exhausted no further application using the same proposal may be made to any other FREC.

3 Obtaining, recording & transporting consent & data

Traditionally qualitative research has been done face-to-face and quantitative research, in particular surveys, have included some postal returns of data. Return of confidential data by post is problematic as post can be lost, intercepted or misdirected. More recently, UWE students and staff have conducted surveys online through the secure Qualtrics platform. This has enabled informed consent to be sought and obtained securely at the beginning of the research and for data to be collected and managed securely.

Increasingly staff and students are conducting qualitative research online or by telephone rather than in-person. This raises issues about the best way to securely obtain and record informed consent, and to securely record and transcribe data. Like post, email can be intercepted or misdirected and so should be avoided for the transportation of confidential information. UWE IT Services provide a number of secure technologies that can support secure online research including OneDrive for storage, and where appropriate sharing, Microsoft Teams for communication, recording and transcription and Qualtrics for data collection. Microsoft Teams is particularly useful as it provides direct transfer to secure storage and a number of other benefits (e.g. notification of recording to participants).

Any research conducted online must be GDPR compliant, respect UWE data protection, research governance and ethics guidance in the same way as research conducted in person. The use of non-secure technologies (e.g. personal mobile phones or other platforms not approved by the University such as Google) raises the ethical risk of breaches of participant confidentiality and should be avoided. Safeguards around managing data need to comply with data protection requirements, but also be proportionate to the degree of ethical risk to individuals, in particular greater care is needed where the potential risk to participants' confidentiality is higher (e.g. HIV status, domestic violence).

3.1 Informed consent

A key principle of ethical research is that human participation should be voluntary and informed. The University therefore expects researchers to provide potential participants with written information in the form of a participant information sheet, and additionally in the case of face-to-face research verbal reiteration, of the participant's absolute right to decline to participate and to withdraw within an appropriate timeframe and without penalty. The University provides templates for participant information sheets and consent forms but recognises that these may need to be adapted to different formats, for example online surveys. Some participants may need information in different formats, e.g. in appropriate languages, in a form appropriate for those with perceptual needs such as visual or hearing impairment, or dyslexia, or graphically represented for those with learning disabilities.

In some situations people may not have mental capacity to give consent either permanently due to conditions such as dementia or temporarily as in some emergency care situations (see Mental Capacity Act 2005). It may be appropriate in such circumstances for an authorised person to give consent on the individual's behalf. There may be some other exceptional circumstances where it is not possible to seek and obtain consent, for example in the observation of crowds. In any situation where individuals are not able to give consent you will need to convince the REC of the ethicality of your proposed research, that there will be clear benefits from the research and that any risks have been minimised.

3.2 Payment for participation in research

There are differing views on the ethics of paying people to take part in research, with particular concern about any payments large enough to induce those in financial need to take part in risker research that they might not otherwise have agreed to. In general, payment is often seen as ethically acceptable as long as the amount is small enough that it is viewed as a mild incentive and/or is simply recompense for the participants' time. For example, it usually would be deemed acceptable to pay a GP for locum cover for a clinical session to enable them to participate in research. Expenses (e.g. travel, parking) are different from payment and should normally be reimbursed if the participant incurs them purely for attending for research purposes.

3.3 Confidentiality, anonymity and the limits of confidentiality

Except in very specific and limited circumstances (see below), participants' data should be treated confidentially, that is, all personal information should be protected and treated as private to the individual unless the participant has given explicit consent for it to be shared more widely. Anonymity is related to confidentiality but somewhat different; it refers to presenting the individual's data in such a way that it cannot be linked back to the individual by others, e.g. by readers of the research report. There are times when with informed consent, participants may be willing to waive anonymity, e.g. in oral history interviews, but they may still want their personal information to be treated confidentially, e.g. by not sharing their contact details.

Before consent is obtained, researchers should inform prospective participants of:

a) Any potential risks that might mean that the confidentiality or anonymity of personal information may not be guaranteed;
b) Which individuals and organisations, if any, will be permitted access to personal information, and under what circumstances such access will be permitted;
c) The purpose for which personal information provided is to be used (e.g. by the researcher to contact them during the study period or if it will be maintained for any reason after the study).

Limits to confidentiality

Researchers should, when seeking consent, make clear the limits to confidentiality, particularly when working with potentially vulnerable individuals or groups - for example when undertaking research with children, or individuals involved in illegal activities. If for example an interview reveals that a participant or another person identified in the interview is in significant danger, the researcher will be obliged to take action in response to that disclosure. Researchers should have established procedures, necessary systems and appropriate contacts in place to activate help and support in the event of a disclosure. If the researcher feels it is necessary to break confidentiality, the participant should normally be informed what action is being taken by the researcher, unless to do so would increase risk to those concerned. Any disclosures of otherwise confidential information should be fully justified in the public interest and researchers must be able to defend their actions fully, for example if required to do so by law or to avert serious harm, and disclosures should only be made to parties empowered to act on the information. [adapted from the *ESRC Framework for Research Ethics*, 2015]

3.4 Recording consent

For in-person research, the consent form template should be used. For online and telephone research, the recommended best practice for recording consent is with Qualtrics. For surveys, the consent form can form the first page of the survey instrument. For qualitative research, a hyperlink can be included in the invitation email and/or participant information sheet to a one page/one item Qualtrics consent form.

It is recognised that there may be some contexts in which other approaches to recording consent may be appropriate. For some busy professionals clicking through to another technology may be a disincentive to participate in the research, or research participants may not be comfortable with this technology. In such cases where the consent form itself does not contain information about the individual (e.g. where the title of the research does not in itself suggest the participant shares a confidential characteristic), a case may be made for allowing the use of email to convey consent.

The more sensitive the data, the greater the need for secure transport and the stronger imperative to avoid sending such sensitive information by post or email. It is important to note that researchers are accountable for the security of research data, and should therefore carefully evaluate the risks, in the light of legislation and UWE policies and guidance, before coming to a decision about what is necessary and appropriate, and setting in place appropriate safeguards.

In some cases, e.g. participants with visual impairment or people who lack literacy, participants in telephone interviews who do not have internet access, oral consent may be appropriate. In these cases, it is important to keep a log of oral consents and to include the oral consent in the transcript of the interview, as the original recording will usually be deleted once the research is complete.

3.5 Recording, storing and transcribing data online

Qualtrics is the UWE approved platform for conducting quantitative research online. Qualtrics is freely available to all UWE staff and students at https://uwe.eu.qualtrics.com/. Regular training courses are available to staff and training is included in many research module teaching programmes.

Microsoft Teams and Blackboard Collaborate are the only approved UWE platforms for conducting qualitative research online. These platforms are available to all staff and students, and the recording function is available on application via the Intranet for staff and via https://go.uwe.ac.uk/teamsrecording for students. Student requests need to include approval by an appropriate named member of staff, usually the research supervisor.

All UWE staff have been given access to a Zoom at UWE Bristol account, but Zoom at UWE Bristol is not currently available to UWE students. Staff must follow the UWE Bristol Zoom Terms of Use, and are required to be a licensed user for any recording purposes.

Interviews and focus groups with external non-UWE participants can be conducted and recorded securely via Microsoft Teams. One-to-one interviews with UWE staff or students can also be conducted and recorded securely via Microsoft Teams, though in these cases the participants as well as the researcher will have access to the recording (until that access is removed by the researcher – advice on how to remove access is available from IT services).

Focus groups with internal UWE participants can be conducted and recorded securely by UWE staff via Blackboard Collaborate. This method is not available to UWE students.

Group interviews and focus groups with UWE staff or students recorded via Microsoft Teams are ethically problematic, as participants will have access to each other's recorded data, and so confidentiality may be breached. Thus, this method will be high risk and should be avoided. If group interviews or focus groups with UWE staff or students via Microsoft Teams are required, then an alternative is to record separately (e.g. with a UWE owned hand-held recording device placed next to the computer, then immediately upload the recording to OneDrive and securely delete from the recording device). We will continue to review this and may be in a position to revise this guidance if alternative capabilities become available.

OneDrive is the only UWE-approved GDPR compliant and secure Cloud location for the storage of data. Do not use Google Drive, Drop-Box or other software to store research data, as these are not secure.

By telephone

If using Teams is not practical (for example the participant is only available on their mobile phone which does not have the Teams app), then staff can use Skype for Business to make and record telephone calls. As students do not have access to Skype for Business, personal mobile phones may be the only practical alternative, but recordings should be uploaded to OneDrive as soon as possible and files on the phone or other recording device immediately securely deleted. Staff and students should be aware that mobile phones are not secure devices so should only be used for low risk research and not ever be used for any highly sensitive/highly confidential data.

In person

Where consent and data are recorded on paper and in person, this information should be transported securely by the researcher to be stored in a locked filing cabinet. Such confidential information should not be transported by external or internal post.

If audio or video recording is undertaken in person, then the files should be uploaded to OneDrive as soon as possible and deleted from the recording device.

Transcription

Transcription may be done in one of three ways. First, the researcher can themselves transcribe the recording. Second, UWE-approved software including Microsoft Teams and Word can provide automated transcription, although researchers need to be aware that the quality of such transcription will be variable and need careful checking and correcting. Third, UWE approved transcription services can be used – advice is available from the Research Ethics Admin Team. Transcripts should be stored securely either directly in Microsoft Teams or in OneDrive.

New platforms or software

We appreciate that new platforms and software you may wish to use are becoming available all the time, but unless the platform or software has been approved by the University, it creates ethical and information security risks. Please seek advice from the Research Ethics Admin Team and/or IT before planning to use any non-approved platform for research. For more information see the Research data security web pages.

4. Safeguarding vulnerable participants in research

4.1 Is it ethical to do research with vulnerable participants?

Often it is ethical to carry out research with vulnerable participants such as children under 18 or adults lacking mental capacity, although there may be some circumstances where it is inappropriate. There are many projects which need to include vulnerable or potentially vulnerable participants in order to gain valuable research information and/or ensure that their voices are heard. This particularly applies where the aim of the research is to improve the quality of life for people in these marginalised groups.

4.2 What do we mean by vulnerable participants?

Research participants may be vulnerable for a number of reasons, and people may move in and out of vulnerability depending on the context or have multiple vulnerabilities. The list below is illustrative but not exclusive:

- Children under 18, both under 16s who can give assent but also require parental/carer consent and 16 and 17 year olds who may be able to give full consent
- Adults who are unable to give informed consent
- Anyone who is seriously ill or has a terminal illness
- Anyone in an emergency or critical situation
- Anyone with a serious mental health issue that might impair their ability to consent at that time
- Anyone where participation has the potential to cause distress, e.g. victims of crime, trauma
- Young offenders and prisoners
- Anyone with a relationship with the researcher(s)

Consider vulnerabilities in terms of groups (e.g. asylum seekers), settings (e.g. rough sleeping) or timing (e.g. after bereavement).

4.3 What are the researchers' responsibility in working with vulnerable participants?

Researchers have the same responsibilities in working with vulnerable participants that they have with any research participants, for example, ensuring informed consent. But there may be additional responsibilities with vulnerable participants. For example consider:

- Balancing safeguarding with the right to be heard.
- How to convey the information for informed consent in a meaningful way (e.g. thinking about language, visual aids)
- Determining if the individual is capable of giving informed consent (e.g. in cases of dementia) with due regard to the Mental Capacity Act
- Obtaining both assent from the participant (e.g. child) and consent from those with designated responsibility (e.g. parent/carer) where the participant is not able to give consent
- Establishing links with those responsible for safeguarding at UWE and in partner organisations and being clear on reporting procedures for any concerns.
- With participants such as children or those who are moving in and out of a vulnerable state, obtaining continuous consent, not just at the beginning of data collection.
- For some projects such as when working with children or vulnerable adults you will need a Disclosure and barring check
- You will need to consider risks specific to vulnerability in your risk assessment

4.4 What might be the specific risks of working with vulnerable participants?

Specific risks for vulnerable participants might include:

- Physical safety of participants
- Research may raise or reinforce traumatic, distressing or painful memories
- Working through gatekeepers/intermediaries and the risks this poses to consent (e.g. undue pressure to participate) and confidentiality
- Participants may share information that raises safeguarding concerns and needs to be reported
- Participants taking part in activities which raise safeguarding concerns (including some but not all illegal activities), which need to be reported
- Participants living outside the UK where safeguarding legislation is different or absent

There may also be risks for researchers:

- Physical safety of researchers (for example, researching with sex workers at night)
- Allegations of inappropriate behaviour
- Potential for researchers to be traumatised by what they see or hear

4.5 How might you need to be prepared?

Consider involving people from the vulnerable community/organisations that support them in the planning of your research to ensure it is appropriate and acceptable. Develop appropriate materials (e.g. separate age appropriate participant information for children and parents/carers, easy read information for adults with learning disabilities). Include means for participant to stop data collection (e.g. interview) easily at any time.

Need to be clear on:

- UWE and partner organisations' policies and procedures on how to respond to safeguarding situations
- Your action plan on how to handle a safeguarding disclosure, including how to maintain confidentiality and the limits of confidentiality
- Who to contact, including in emergency situations and out-of-hours
- How to make and keep records (what form, where stored, what to include)
- Available sources of support for participants
- Who to talk to afterwards if you need to debrief, and the bounds of confidentiality on that

4.6 Covert research or research involving deception

In general, good ethical practice requires participants to be fully informed about the research they are participating in. There may be some rare occasions (e.g. psychology experiments) when covert research or research involving some degree of deception is ethical if the risks are minor and the benefits of the research outweigh the risks. In such cases, participants should be considered as potentially vulnerable and special care given to their welfare, for example offering a debrief to participants after the data have been collected. Useful guidance on deception in research can be found in the British Psychological Society Code of Human Research Ethics.

4.7 UWE key links and resources

- If you are uncertain or want support in planning the safeguarding of vulnerable participants in your research, contact your Faculty Research Ethics Committee chair or the University Research Ethics Sub-committee chair via researchethics@uwe.ac.uk.
- UWE webinar on safeguarding vulnerable participants in research (July 2021)

- UWE Safeguarding information is on the external website or on the Intranet for staff
- Advice on involving people in research is available from People in Health West of England

4.8 Selected national resources

- ESRC (2022) Research with potentially vulnerable people
- NIHR (2021) NIHR Safeguarding Guidance
- Nuffield Council on Bioethics (2015) Children and clinical research: ethical issues
- UK Collaborative for Development Research safeguarding resources including 'Guidance on Safeguarding in International Development Research'.

5. Evaluation and audit studies

5.1 What are evaluation and audit?

Evaluations generally seek to systematically assess the efficacy, efficiency or effects of a particular service or policy. There are different understandings of evaluation but often evaluation is aimed at improving services. Evaluation may or may not be considered research depending on the context in which it is done and which organisation it is connected with. A service evaluation done in the NHS is not normally regarded as research by the NHS but will be considered research by UWE if done by University staff or students.

Audit is commonly seen as measuring a service against set standards. Again, audit in the NHS will not be considered research by the NHS, but might be considered research if done by a UWE student as part of a dissertation module. Audit within UWE, for example, assessing the extent to which a professional service meets its targets, will not normally be considered research and will not require ethical review.

If you are unsure whether your proposed activity is an audit or service evaluation then please seek advice from Researchethics@uwe.ac.uk.

The Health Research Authority provides a tool for those working in an NHS setting to help decide whether or not a study is research, evaluation or audit: http://www.hra-decisiontools.org.uk/research/ . If this tool determines that HRA approval is not necessary, you may still require ethical approval from UWE.

Studies that are designed to make links to existing personal data held for example by the University on student data systems or by HR will normally require ethics review. If you are unsure whether or not your proposed activity is research please seek advice from Researchethics@uwe.ac.uk.

5.2 What kinds of methods are used in evaluation studies?

A range of methods may be used to conduct an evaluation. Existing data sets may be analysed or new data generated. It is common for survey methods, interviews, focus groups, action research, document analysis, secondary data analysis or mixed methods to be used. It is not the method(s) which determines if an evaluation is research, rather it is a question of the purpose of the activity and the type of data that will be collected.

5.3 Does an evaluation study require ethics review by a research ethics committee?

Yes, any evaluation study taking place within the University or conducted by a member of UWE staff or student, and where the purpose is to generate new knowledge (e.g. intended for external

publication) or fulfil a student's requirements in a University programme or module, requires ethical review.

The only evaluation studies which do not require ethical approval are those which are for University administrative purposes only and meet the University's data protection guidance. For example, a customer satisfaction survey, or module evaluation, which does not collect any personal data, will not normally be regarded as a research study. Personal data includes name, email address, home address, student or employee number, job title or any other identifier.

If you are unsure of whether or not your proposed study requires ethics review, please seek the advice of from Research.Ethics@uwe.ac.uk.

5.4 What kind of ethical review do service evaluations in the NHS require?

If a UWE staff or student evaluation is carried out in the NHS and involves NHS staff and/or patients or their data, then it will require UWE ethical review even if it does not require NHS ethical review. It is also important to note that it may require NHS R&D approval as well using the same IRAS application system, even if it does not require NHS ethical review.

5.5 What kinds of ethical issues arise in relation to evaluation studies?

As with other types of research there may be ethical issues to consider including for example:

- recruitment and selection of participants
- procedures for seeking informed consent
- anonymisation of data
- confidentiality
- risks to participants/risks to researchers
- data protection
- data storage and data management
- data sharing and archiving
- data disposal

Applications for ethical review should discuss all such ethical issues and the measures the evaluator will take to address them.

6. Projects without human participants

Most applications for ethical review and approval involve human participants as research subjects, but a significant number do not. This section aims to help researchers think through the issues and submit an appropriate application for ethical approval.

The aim of the following list of types and examples of ethical issues for research without human participants is to aid reflection and ensure that all such issues are considered, irrespective of where the research is carried out. The list is not comprehensive nor exhaustive, and the final responsibility to consider and declare all relevant ethical issues still lies with the researcher.

Consider any ethical issues concerning:

- ***Risk to the research team and any other people*** impacted by the research project, for example, involving hazardous materials, or travel to possibly risky locations. See the UWE Risk assessment guidance on the Intranet.

- ***Animal welfare and Animal by-products***. For further information, contact the UWE *Research Governance Team* at researchgovernance@uwe.ac.uk.
- ***Environmental impact***. Is there a risk that your research could contribute to any kind of pollution, environmental degradation, flooding, etc? Consider any processes, laboratory procedures, materials and equipment you are planning to use in your research – what are the implications for the environment, and long-term sustainability?
- ***Infringement of the law***. Might your research break the law, encourage others to do so or uncover illegal activity?
- ***Conflicts of interest***. Do you, or any of the research team, have a conflict of interest or loyalty that might impede or demotivate you from properly fulfilling the aims of the research or from carrying out the research in an ethical manner?
- ***Financial self-interest***. Do you or any member of the research team have a personal financial interest in the conduct or outcomes of the research (including intellectual property (IP) beyond UWE)? If so, then you must declare this within the application form.
- ***Impact on society***. Could any conduct or outcome of your research contribute to causing conflict within society, be it at the local, national or international level? Might it escalate tension between different ethnic, religious, national or political groups?
- ***Reputational damage*** to UWE, Bristol. Could any aspect of the conduct of the research cause you and/or the University to be justly criticised or viewed in a bad light?
- ***When anonymised datasets are aggregated***, it is possible to re-identify sources of information that had been de-identified in the stand-alone dataset? For example, data collected for different purposes by different state agencies might if aggregated, pose a danger of data-linkage making re-identification. This can be a particular problem in projects involving the use of artificial intelligence (AI) in processing large anonymised data sets. Even though your research might not directly involve human participants, you must give careful consideration to this potential danger and the possible need to gain informed consent from such indirect participants.
- ***Ethical issues associated with project partners.*** Are any of those involved in the project, such as companies, or countries, likely to throw up significant ethical issues? Have you considered issues such as any sanctions imposed, record of legal or regulatory breach, human and animal welfare and environmental record of those you are planning to work with? If you need further advice in this regard, contact the UWE Research Governance Manager.

7. Secondary analysis of existing data

All research potentially raises ethical issues, including secondary analysis of data previously collected for other purposes. This may be official statistical data (for example census data, other national or local government administrative statistics), data gathered by commercial organisations or data from previous research studies. They are often quantitative, although secondary analysis of qualitative data is becoming increasingly common.

Secondary analysis of previously collected data may be highly ethical as it potentially maximises the value of public data and reduces the burden on research participants. But it is only ethical if the benefits outweigh the risks. Therefore, as with all research, careful thought must be given to protecting the rights of the participants and minimising any potential risk or harm to them. Confidentiality is key, and is an increasingly complex area with the advent of artificial intelligence

and other big data technologies that may risk individuals being re-identified from supposedly anonymised data sets.

Some data sets are already protected by strict ethical protocols, for example data sets available through the Office for National Statistics or the UK Data Archive in which case ethical risks are already well managed by the host organisations.

Other data are freely available in the public domain where individual will not have an expectation of privacy or confidentiality, for example published biographies, newspaper accounts, transcripts of testimony to public inquiries or published minutes of official meetings. In these cases there is no need to treat the information as confidential or seek informed consent for secondary analysis.

The use of secondary data in other circumstances must meet some key ethical considerations:

- Data must be de-identified before release to the researcher
- Consent of study participants must be demonstrated or reasonably presumed to follow from the original consent given
- Outcomes of the analysis must not allow re-identification of participants

Use of the data must not raise any likelihood of damage or distress to the original participants.

8. Use of drones (unmanned aircraft systems)

All drone (unmanned aircraft systems) use must follow the UWE Bristol Safe Use of Unmanned Aircraft Systems (drones) policy and Operations manual (UWE Bristol log-in required). Any use of a drone for research that might impact on people is considered human participant research also needs to be submitted for ethical review. This includes, for example, using a drone to film crowds or streets where people may be walking.

For any use of drones that might impact on animals, you will need to apply to the Animal Welfare and Ethics Sub-Committee.

9. Ethical issues in the use of social media in research

This guidance is designed to inform researchers and ethics committee members about some of the potential ethical implications arising from the use of social media in research. For the purposes of this guidance a broad definition of social media is adopted, encompassing a range of different platforms and networks. The term social media is an 'umbrella label' that covers a broad range of internet and web-based sites and services that connect individuals and groups, for example *Facebook*, *Twitter,* and *Linked-In*. Specific issues to consider in social media research include informed consent, confidentiality and privacy.

9.1 Informed consent

A central issue in relation to any research using human participants is to ensure appropriate measures are in place to ensure informed consent will be obtained before the research takes place. This question can be difficult for research involving social media.

General ethical principles and UWE's requirements for seeking ethical approval for projects mandates that, unless consent has been sought, observation of public behaviour needs to take place only where people would 'reasonably expect to be observed by strangers.' This requirement essentially vetoes observation in public spaces where people may believe that they are not likely to be observed. An

obvious example may be public changing rooms, or gyms. The same principles apply to research from social media sources.

Researchers should demonstrate respect for participants' expectations of privacy and consider the extent to which observations may have potentially damaging effects for participants even where online data can be considered in the public domain. In all other circumstances valid consent is needed where it cannot be argued that online data can be considered in the public domain.

Even where websites or social media platforms seek to disclaim responsibility for the privacy of its users, researchers must be aware that it is usual for individuals to access web sites without reading instructions, explanations or terms and conditions. Participants may therefore nominally have 'consented', but although *consent* is provided it is not *informed consent*.

For anonymised-at-source non-sensitive data, consent may be considered to have been given by the act of participation or by ticking a box for example. However, if anonymised-at-the-source data covers sensitive topics such as sexual behaviour clear and specific consent processes will be required.

In deciding whether informed consent can be considered to have been obtained, the questions that need to be thought through in the research design should include:

- Establishing whether the data can reasonably be considered in the public domain;
- Other than where this is the case, how are research participants to be made aware that they are involved in academic research?
- How will a Participant Information Sheet be provided and informed consent obtained?
- How can participants withdraw from the research?
- Can their contributions be removed and/or returned to them?
- If any of the above are impracticable, can 'tacit consent' be assumed, e.g. from the fact of participation?

9.2 Confidentiality and Privacy

If desired, can the identity or plural identities ('physical' or virtual) of research participants be kept confidential?

- Researchers should be aware that is impossible to maintain complete confidentiality of participants because the researcher is not in charge of the network/social media platform. For example, law enforcement bodies may have a statutory right to request access to the data.

Will it be possible to guarantee privacy?

- Internet communication is often more visible, traceable and permanent, so it may not be definitively possible to guarantee privacy. However, all efforts should be made to allow for this.

Is it possible to maintain a distinction between 'private' and 'public' spaces?

- It is arguable postings to discussion groups do not automatically count as public activity. When constructing research using discussion groups, any requirement for consent by participants obviously needs to be tempered by a consideration of the nature of the research, the intrusiveness and privacy implications of the data collected, analysed and reported, and possible harm that could be caused by the research.

How ‘traceable’ is the data by non-researchers and non-participants?

- Researchers should avoid using quotes that are traceable by typing it into a search engine unless the participant has fully consented. The researcher should consider the use of pseudonyms and paraphrasing of quotes to address this. If direct quotations are necessary, then consent of those sampled should be sought.

Are there any potential means of identification of individual participants by means of linking (or disaggregation) of publicly available data sets created by others?

- Sometimes when anonymised datasets are aggregated it is possible to re-identify a participant. Where de-identified datasets are being used without the consent of the original subjects (for example, many sources of government data that are available online are using data collected for one purpose by State agencies and making this data available, including to researchers. In this instance there is no consent from the original data subjects and therefore if there is a danger of data-linkage making re-identification possible careful consideration of the ethical dimensions and the need to gain informed consent from such potential participants must be considered).

9.3 Transparency/covert research

This type of research is not confined to social media, however social media technology makes covert research possible in new ways. If covert research is part of the project design, how is this justified?

- For example, projects where research aims and objectives signal clear contribution to the ‘greater good’. However, the ethical considerations must be given a high priority. Caution should be exercised and strong justification will need to be provided in the ethical approval application, together with a risk assessment.
- Will the researcher adopt a pseudonym or ‘alternative identity’ (e.g. an avatar)? Does this pose any additional risks to the researcher or the participants?

9.4 Anonymity and authenticity

All reasonable efforts should be made to ensure the highest level of anonymity possible unless specific consent has been obtained for identifying information to be made public.

Particular attention should be given to the following issues:

- Is interaction between participants possible ‘outside’ the research setting? This may skew the research and needs to be taken into account in the project design.
- Might it be possible for somebody to participate in research in order to identify other participants for contact outside of that context? How can this be mitigated in the project design?
- Can the identity and social characteristics (age, gender, etc.) of research participants be verified? For example, what if a child lies about their age and pretends to be an adult?
- Direct quotations should only be used where explicit consent has been obtained.
- How can the contribution of research participants be properly acknowledged?

9.5 Protection of participants

Are there any risks for participants? The researcher should be clear about the extent to which their own collection and reporting of data obtained from the internet would pose additional threats to

privacy over and above those that already exist. Researchers should take appropriate actions towards harm minimisation such as removing authors name and @tag etc.

Particular consideration should be given to whether particularly vulnerable participants may be involved and how will their safety and wellbeing be assured? For example, research involving social media groups who support victims of crime or children. Is it possible to identify any vulnerable participants? If so, how can this be overcome in the research design?

9.6 Selected national resources

Townsend & Wallace (2016) Social Media Research - A Guide to Ethics

UKRI/ESRC (2022) Internet mediated research

10. Researching within one's own organisation (insider research)

A number of students (particularly those pursuing professional doctorates) and some staff wish to research within their own organisations due to the practical advantages of contextual knowledge, ease of access to gatekeepers and participants, topicality and opportunity to directly influence policy and practice. There are, however, several potential ethical issues in researching one's own organisation which need to be considered carefully in planning and reviewing such research.

10.1 Role conflict between organisational role and researcher role

A key role conflict issue is the potential for a power inequality between the researcher and the researched, particularly if the researcher is in a more senior position in the organisation. This can be especially acute if the researcher has direct or indirect line management responsibilities for some or all of the potential participants. Junior staff may feel implicitly pressurised to participate and, if they do, may not feel able to answer all questions fully or honestly. Similarly, they may not feel able to withdraw from the study or to question the presentation of the findings or the analysis, conclusions and/or recommendations. There is the potential for a senior manager/researcher to use the findings on such insider research to implement changes to the organisation that may disadvantage the participants although this may not have been explicit in the research.

10.2 Consent

Obtaining truly voluntary informed consent is often a potential issue in researching your own organisation, again most acutely for anyone in a senior position. Potential participants should never be approached directly by their supervisor or line manager, and may feel unable to decline the request to participate due to concerns that it may adversely impact management perceptions of their commitment and thus their careers. Even with the best intentions and clear statements about the voluntary nature of participation, the power inequality between researcher/senior manager and junior staff may led them to feel compelled to participate. This may be particularly problematic in small organisations where individual anonymity may be more difficult. If the research is to go ahead ethically, the researcher may need to think deeply and creatively about how to construct both consent processes and research methods that minimises any such concerns, for example, invitations going out from the researcher's student email account not their organisational one, and data being collected anonymously via Qualtrics rather than in person.

10.3 Maintaining confidentiality and anonymity

Maintaining confidentiality and/or anonymity of participants may be more difficult when researching within one's own organisation as individuals from within the organisation may well wish

to read the report and their familiarity with their peers means they may recognise the contributions of participants even when they have been anonymised. Particular phrases or perspectives may identify individuals even if not named or their organisational position specified.

10.4 Consideration of alternative settings for research

Researchers should always consider the issues discussed above and whether the research could not be done in alternative but similar organisations where such role conflicts will not exist. If after consideration, you still wish to pursue insider research, the REC is likely to review carefully whether your rationale is justified and whether you have sufficiently mitigated the risks in your proposal.

10.5 Reference

Toy-Cronin, B. (2018) Ethical issues in insider-outside research. In R Iphofen & M Tolich (eds.) *The Sage Handbook of Qualitative Research Ethics* London: Sage Publications Ltd.

11. Security sensitive research

This guidance relates to research that may be deemed to be security sensitive and thus fall under the provisions of the Counter Terrorism and Security Act 2015 (the Act). Under the Act, relevant higher education bodies must have due regard to the need to prevent people from being drawn into terrorism (known as the 'Prevent Duty'). Compliance with the duty is monitored by the Office for Students (OfS). UWE Bristol complies with the Duty under the provisions of its Safeguarding Policy within which context this guidance is placed.

11.1 Summary of specific provisions for security sensitive research projects

- At all times, researchers should inform themselves and be mindful of relevant legal obligations under the Prevent Duty when planning and conducting security sensitive research;
- RESC will maintain a record of all applications for ethical approval considered by the Committee to amount to security sensitive research;
- Applicants making an application for ethical approval should indicate on their application forms that their project may amount to security sensitive research;
- Where a project involves security sensitive research the application will be referred to RESC from the FRECs;
- That once so identified the Chair of RESC will notify UWE Bristol's Prevent Lead of the project. If provided, comment from the Prevent Lead will be taken into account by RESC before Chair's Action is taken;
- All staff involved in security sensitive research, and who make an application for ethical approval, must complete the e-training module The Prevent Duty in Higher Education: An Introduction prior to approval being awarded for the project;

11.2 The scope of security sensitive research

It is impossible to provide an exhaustive list of research that may be deemed security sensitive. However, the following is indicative of what might be considered security sensitive research:

- Projects concerning extremist religious groups, including where accessing their materials may be committing an offence under the provisions of section 58 of the Terrorism Act 2000 and the Terrorism Act 2006 if not confined to use for purely academic research purposes.

- Projects concerning organisations that could potentially be involved in acts that could breach counter-terrorism legislation under the Terrorism Act (2006), for instance extremist animal rights or Far Right groups;
- Projects concerning cyber-terrorism;
- Projects undertaken for government departments concerning or including sensitive topics, for instance military procurement or weapons technology;
- Online projects which involve researching potentially sensitive extremist websites;
- Projects concerning making direct contact with extremist groups or individuals;
- Research which has the potential to be used for purposes unintended by the researchers in ways which threaten security despite this not being the intention of the researchers. An example of this type of research may be projects concerning novel IT encryption methods.

UG or PGT student projects that involve only public domain sources, for example, literature reviews of published academic papers, will not normally be considered security sensitive research even if they include reference to the terms above. Ethical approval forms or records by supervisors of student projects should record if the student's project may legitimately require accessing potentially security sensitive material that is already in the public domain to protect the student if their internet search triggers any security interest. Any such student projects should be notified to the UWE Bristol Prevent Lead who will keep a register of security sensitive research.

11.3 How does RESC manage security sensitive research applications & protect researchers?

Researchers making an application for ethical approval in relation to projects that may be considered security sensitive research should apply in the usual manner. If the applicant is aware their project is security sensitive this should be mentioned on the application form.

If the applicant is unaware of, or fails to mention, a potentially security sensitive aspect to their project, the scrutineers will use their best endeavours to identify such projects during scrutiny. All applications to FRECs identified as involving security sensitive research will be referred to RESC, either by self-notification by the applicant or by identification during scrutiny. Once referred to RESC the application will be scrutinised in the usual way and a decision will be made by RESC Chair's Action. If approved, RESC will be asked to ratify the decision at the next quarterly RESC meeting.

In the case of a project identified as involving security sensitive research the RESC Chair will inform UWE Bristol's Prevent Lead of the project and if necessary discuss with the Prevent Lead aspects of the project that require risk assessment over and above that usually undertaken as part of RESC's ethical review process to the extent that such discussion enables UWE Bristol's Prevent Lead to discharge UWE Bristol's duties pursuant to the provisions of the Act.

As part of RESC's ethical approval process, all proposed research projects are risk assessed in terms of the safety of research participants, the researcher and UWE Bristol. This risk assessment includes (but is not restricted to) identifying projects that may be security sensitive and to consider associated risks. This, together with the notification to UWE Bristol's Prevent Lead ensures RESC does not exceed its ethical review remit whilst facilitating UWE Bristol's compliance with its statutory Prevent Duty. This process enables UWE Bristol's Prevent Lead to consider:

1. The application in terms of the counter-terrorism risks known to UWE Bristol;
2. What support might be offered; and
3. How UWE Bristol might ensure that its usual safeguarding arrangements are followed taking into account the details of the proposed research.

RESC will maintain a record of all projects applying for ethical approval involving security sensitive research but the formal UWE register of such projects will be held by the Prevent Lead. If statutory enquiries relating to the Prevent Duty are made by external agencies information contained on the record may be made available to those agencies insofar as UWE Bristol is required by law to produce it. The research lead will normally be told of this action. By keeping a register UWE Bristol is able to monitor the prevalence and potential risk of identified projects.

11.4 Application procedure for security sensitive research projects

For staff and postgraduate research students:

1. Applications for ethical approval for potentially security sensitive projects should be made by the usual processes;
2. If a researcher indicates that security sensitive research is being undertaken on the application, then the application should be sent for approval to RESC, rather than the relevant FREC.
3. If a researcher does not indicate that the project involves security sensitive research the application will be forwarded by the FRECs to RESC for scrutiny;
4. RESC scrutiny and Chair's Action will be undertaken in the usual way;
5. The Chair of RESC will inform UWE Bristol's Prevent Lead of the project to enable a risk assessment to be undertaken in relation to UWE Bristol's Prevent Duty and for the Prevent Lead to keep a register of security sensitive research in a secure database;
6. A record of the project will also be held by the research ethics administration team in RBI on their secure database.
7. All staff, PGR students and their supervisors who are conducting research that may be regarded as security sensitive are required to complete the Prevent training module before ethical approval can be given.

For taught students (PGT and UG)

1. As a general principle RESC does not encourage students on taught programmes to design and undertake any research involving human participants falling into the category of 'high risk'. This includes security sensitive research.
2. For students undertaking projects which might be considered security-sensitive in nature, the supervisors must make an early judgement regarding the appropriateness of the topic and advise students. An auditable record should be kept of such advice. If the work is relying solely on secondary academic sources, then it would not normally be regarded as security sensitive research. However, if the student were intending to visit extremist websites or speak to individuals of concern, then it should be considered as potentially security sensitive.
3. The supervisor at this stage can do two things: 1) make a decision (perhaps in consultation with colleagues) that the work should not go ahead, or 2) recommend that the work should proceed. It is envisaged by RESC that projects in category 2) will be extremely rare.
4. If the supervisor decides the project falls under category 2) the project must be regarded as 'high risk' and will require full ethics review by RESC.
5. All supervisors (or equivalent) conducting research that may be regarded as security sensitive are required to complete The Prevent Duty in Higher Education: An Introduction before ethical approval can be given.
6. The Chair of RESC will inform UWE Bristol's Prevent Lead of the project to enable a risk assessment to be undertaken in relation to UWE Bristol's Prevent Duty and for the Prevent Lead to keep a register of security sensitive research in a secure database.
7. A record of the project will also be held by the research ethics administration team in RBI on their secure database.

8. All staff, PGR students and their supervisors who are conducting research that may be regarded as security sensitive are required to complete the Prevent training module before ethical approval can be given.

11.5 Advice, support and training

- The Prevent Duty in Higher Education: An Introduction training module is available to staff (requires Staff login);
- Universities UK (2019) published updated Oversight of security-sensitive research material in UK universities: Guidance.
- If you have any concerns about whether or not your research is security sensitive, please speak to your FREC Chair for advice or contact the RESC Chair via: researchethics@uwe.ac.uk.

12. Research sponsorship

12.1 What is a Research Sponsor?

The Research Sponsor takes ultimate responsibility for the conduct and integrity of the research, ensuring that research projects have adequate indemnity/insurance arrangements, are registered, are approved by the appropriate bodies and are subsequently monitored.

12.2 Who acts as a Research Sponsor?

UWE Bristol will normally act as Research Sponsor for research conducted by its staff and students. However, there are circumstances when this may not automatically apply:

- When a staff member has an NHS contract, and is employed within the NHS where the research is being carried out, it would normally be expected that the employing Trust would act as Sponsor for the research.
- When a student is an NHS employee where the research is being conducted, it is normally expected that the employing Trust would act as Sponsor for the research.
- Exceptionally it may be appropriate for joint sponsorship of a study.
- When research is being funded by a commercial organisation, they may act as the Sponsor.
- UWE Bristol rarely acts as Sponsor for drug clinical trials but may act as Sponsor for other clinical trials. Where the member of staff or student has a clinical contract, the Sponsor will normally be their employing Trust. A Trust may also take the Sponsor role if they hold the funding award.

12.3 Do I need a Sponsor for my research?

All research falling under the remit of the Secretary of State for Health and Social Care must have a formal Sponsor. This includes all research in health and social care that involve NHS patients, their tissue or information, and there are similar requirements for research involving social care practitioners, clients and resources. UWE Bristol acts as Sponsor for all staff and student research that does not already have an external Sponsor such as an NHS Trust (that may be hosting the research), a pharmaceutical company, charity or other university.

12.4 If your project involves human participants who are NHS patients

1. You will need to apply for NHS REC ethics approval through IRAS. To do so, you will need sponsorship arrangements confirmed.
2. If you are a member of staff, you will need to contact the FREC Officer to notify them of your

intention to submit an IRAS application. Once your application is completed, you will need to transfer it to the Chair of FREC for them to view and comment on your application. This is to ensure that there are no potential risks or issues which need to be raised before sponsorship is agreed. A copy of your final IRAS application and NHS REC approval will need to be submitted to the FREC Officer.

3. If you are employed on an NHS contract where the research will be hosted, you should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as Sponsor for your study.
4. If you require UWE Bristol to act as Sponsor, then you will need authorisation from the Associate Dean Research for this on your IRAS form. The FREC Officer will guide you through this and arrange for a Sponsor letter to be prepared. After this you can submit your IRAS form to the NHS REC for approval.
5. If you are a student, you will first need your supervisor to approve your IRAS application before approaching the FREC Officer or seeking authorisation from the Faculty.
6. If you are a student employed on an NHS contract where the research will be hosted, you or your supervisor should approach your NHS employer (R&D office or equivalent) to see if they are willing to act as Sponsor for your study.
7. Once you have received your NHS REC approval, please send a copy of the approval letter together with any associated documentation (i.e. consent forms, information sheets etc) to the FREC Officer.

12.5 If your study involves the use of human tissue, you will additionally need to

1. Familiarise yourself with the Procedures and guidance for human tissue research at UWE Bristol.
2. You will need to register your research on the UWE Bristol Human Tissue Research Register and submit copies of your NRES application and approval to researchgovernance@uwe.ac.uk.

13. What else do I need to do in addition to ethical approval?

You will also need to consider the following:

- Only carry out research that is covered by your ethical approval.
- If things change (e.g. changes to participant groups, protocols, time extensions) then let the REC know by completing an amendments form. This can often be processed quite quickly.
- You can only use data for which you have consent and ethical approval. If you want to use data collected from one project for a different project you can only do so if the participants have consented to the secondary usage and this has ethical approval.
- If your research involves external funding and/or contracts with partner organisations, you will need to seek advice from the UWE Contracts Team.
- If any third party (i.e. any person or institution external to UWE) is involved in collecting and/or sharing personal data, you will need to seek advice from the UWE Data Protection Team.
- **Research Data Management Plans**
  A research data management plan is a mandatory document drawn up at the start of the research process which outlines how all research data will be generated or collected, managed, stored and preserved, shared or disposed of. You should complete this at the outset, and update as appropriate as the project progresses (and upload to the Research Governance Record for the research).
- **Code of Good Research Conduct**

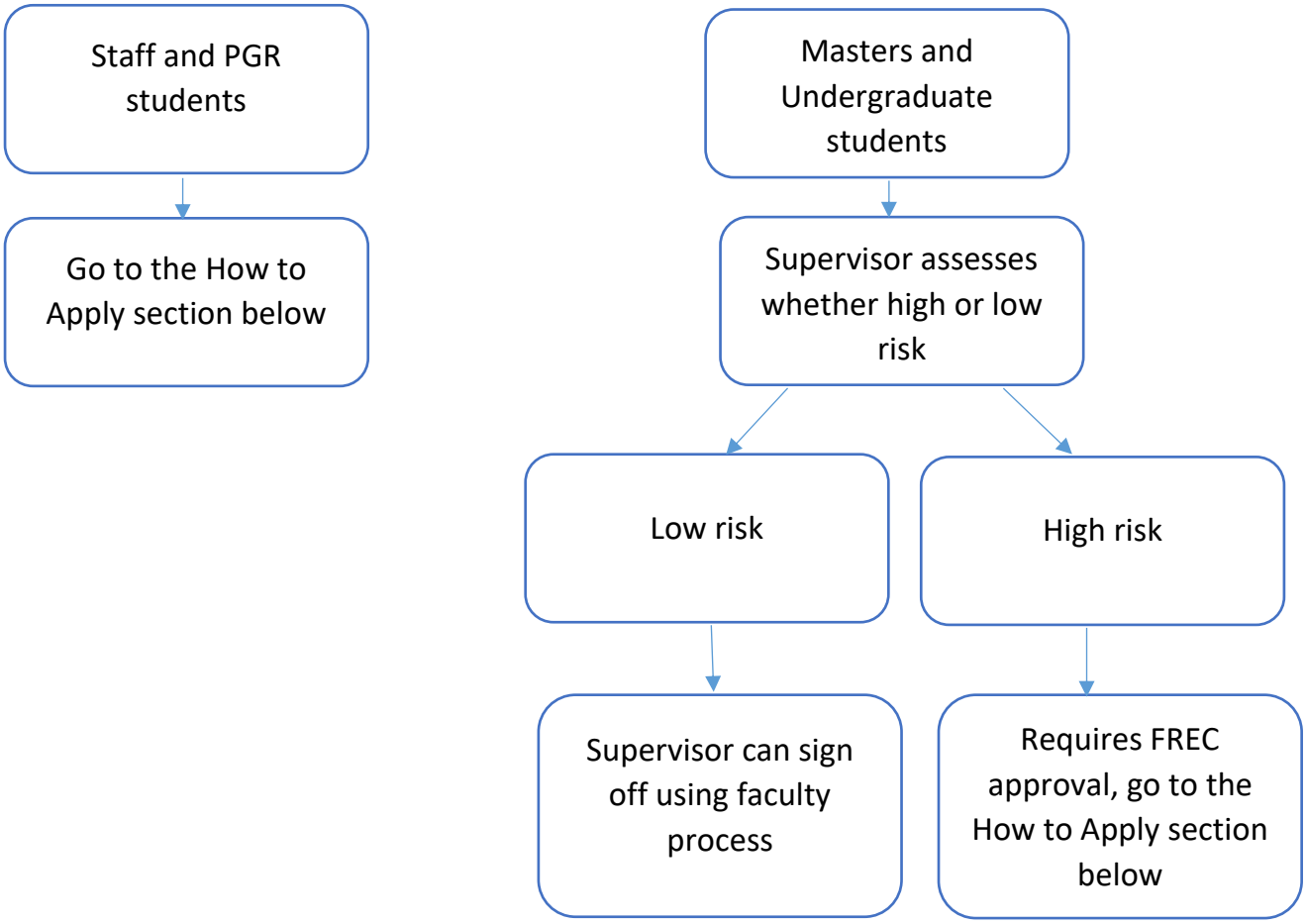
The Code of Good Research Conduct sets out the University's requirements and expectations of researchers.

- **Health and Safety / Risk Assessment**
  Risk assessment is a required process of identifying the hazards present in the workplace or in work activities, and evaluating the extent of the risk involved. Its purpose is to either eliminate the risk of injury or to reduce the risk of injury to a safe level.
- **Intellectual Property**
  For more information see the Intellectual property web pages.

Annex 1

How to Apply for Ethical Approval

If you are conducting research involving human participants, and/or their tissue or data, you should follow the appropriate route indicated below:



How to apply

For FET staff and doctoral students please use the online system using the link below:

New online ethics application (for FET staff only)

Postgraduate research (PGR) students who do not have a UWE Bristol staff email account will need to request access to the system by contacting the Research Ethics Admin Team (researchethics@uwe.ac.uk).

All staff and doctoral students in the Faculty of Arts, Creative Industries and Education (ACE); Faculty of Business and Law (FBL); the Faculty of Health and Applied Sciences (HAS); and Professional Services, should continue to use the current process linked below. **ALL** undergraduate and postgraduate taught students whose research has been assessed as high risk should also use the process and form linked below.

Useful links to application form and amendment form can be found here

Complete the application form, providing the following:

What documentation do you need to provide?

You are required to provide the following details:

- Research proposal or project design
- Participant information sheet and consent form
- Staff and postgraduate research (PGR) students must provide a UWE Bristol privacy notice
- Undergraduate and M-level students should follow the Data Protection guidance for UWE Bristol students
- Questionnaire/survey/indicative interview topics or questions
- External ethics approval and any supporting documentation (if appropriate)

When do you need to apply?

You must allow six weeks for your application to be processed. Please note, over the summer and the Christmas and Easter vacations, your application may take up to eight weeks when scrutineers are not available to review applications.

How will your application be reviewed?

Applications are logged by the Research Ethics Administrative team, and sent out to members of the Ethics Committees for scrutiny. Scrutineers use a checklist, Scrutineer's Review Form, to ensure that applicants have addressed the necessary points in their applications. Comments are collated and then passed to the Ethics Committee Chairs to make a decision on approval. Often further work or clarification is needed before full approval can be given (make sure you factor this into your timetable).

You cannot start collecting data until you have full ethical approval for that activity.

Potential outcomes of an ethics application are:

- full approval
- approval with conditions
- revise and resubmit
- not approved.

You will be given feedback to help you to make your application better. It is very unusual for an application to be 'not approved'.

Once you have full ethical approval:

- Make sure that what you do is only what you have been given approval to do.
- If you haven't got consent from your participants to share your data or use in ways not specified in your consent form, you can't do it!

Are you GDPR compliant?

- Templates for participant information sheets, consent forms and a privacy notice for staff and postgraduate research (PGR) students are available on Policies, procedures and guidance. These are GDPR compliant and should be used.
- Undergraduate and postgraduate taught (Masters) students should refer to the Data Protection guidance for UWE Bristol students.
- All staff and postgraduate research (PGR) students undertaking research can refer to the Data Protection Research Standard for general GDPR guidance. However, please be aware that information about ownership of data has changed. See the Data Protection guidance for UWE Bristol students.
- Participant information sheets, consent forms and other relevant documentation must include the UWE Bristol logo (see UWE Bristol logo usage).

The NHS and other research ethics committees

If your research project involves NHS patients, service users, organs, tissue, data or other bodily material, or is to be conducted on NHS property, please refer to our Health and Social Care research page.

If you have ethical approval from another external research ethics committee, for example from another Higher Education Institution, you will need to email this to your FREC or to RESC for ratification at researchethics@uwe.ac.uk.

Amendments

If things change, you need to let the Committee know, and may need to apply for further approval, for example changes to participant groups, protocols, or extensions. You can do this by completing an amendment form. This can generally be processed quite quickly.

Urgent approval in exceptional circumstances

If you need an urgent decision on your application, a special request for exceptional approval can be made by contacting the Research Ethics Administrative team at researchethics@uwe.ac.uk, tel: +44 (0)117 32 81167. This option is only available to staff and not to undergraduate, postgraduate taught or postgraduate research students, and cannot be used to support a retrospective ethical approval.

If a project has multiple methods of data collection that do not require fast approval, then the researcher should request urgent processing only for the relevant part.

The researcher must accept that there are no guarantees that an urgent decision can be made by their deadline. It is dependent on the capacity of others.

If the application is of poor quality, then it will cease to be treated as urgent.

The RESC/FREC reserves the right to delay processing urgent applications if the necessary administrative and scrutiny resources are not available to reach a decision with the urgency requested.

Annex 2

FREC Chairs' top tips for getting your ethics application approved quickly

Application for ethics review are often delayed due to incomplete or inconsistent documentation. We asked our FREC Chairs for their top tips in getting your application approved quickly.

1. **Make sure you have carefully completed all sections of the application form** and included all necessary supporting documentation (consent form, participation sheet, privacy notice, indicative survey/interview questions)
2. **Read and follow all relevant sections of the Handbook**, for example on obtaining and recording consent and data (e.g., say you will store data on UWE OneDrive not a password protected personal computer).
3. **Consider power dynamics in recruitment and consent issues carefully.** If there is a relationship between the researcher and the subjects, consider how you will avoid this colouring the participants ability to say 'no'. An example particularly common in University research is the power imbalance between staff and students, especially where the students are on a credit-bearing module run by the researcher. If researching with children, plan to get 'double' consent– i.e. from both the parents/guardians and the children – even if they are small children they still need to be asked.
4. **Make sure that for every box checked for methods used in section 5.1, each method has a corresponding, clear description in section 2.2**, particularly in relation to the request "Please describe the research methodology for the project".
5. **Proofread the application form and supporting documents** for typos, errors and inconsistencies between documents (e.g., if you say in the participant information sheet that participants can withdraw up to three weeks after signing the consent form, make sure the consent form says the same thing).
6. **Use/adapt the templates for participant information sheet, consent forms and privacy notices.** For example, avoid multiple tick boxes on the consent form as one signed consent should cover all essential aspects of consent (including if appropriate future secondary analysis of the data) although some limited additional consents may be appropriate (e.g. consent for use of photos in future publications)
7. **Ensure your participant information sheet and consent form are written in age/audience appropriate style.** Avoid academic jargon. Use photos and illustrative pictures where appropriate (e.g., for children and those with poor literacy).
8. **Make sure that all forms of participant recruitment and inclusion identified in section 3.2 are included and explained in the description of the methods in section 2.2.** For example if you say you will use e-mails or telephone to contact participants make it clear how you will access their e-mail addresses/telephone numbers. If social media is to be used say which social media and how it will be used.
9. **How do you know vulnerable people won't respond?** You might state that no vulnerable people will be included in your sample, but can you really be sure of this? How will you know that you recorded informed consent unless you select your participants and screen them in some way?

10. **Are some demographics excluded, perhaps on the basis of their protected characteristics?** Can people with visual impairment, hearing loss or limited mobility etc take part? If not, you need to explain why they are excluded – or could you change your protocol to make it more inclusive? Excluding demographics from research leads to entrenched bias.
11. **Do you need assistance?** If in doubt seek assistance from the relevant FREC chair or email researchethics@uwe.ac.uk

Annex 3

Use of Identifiable Patient Data

a) Identifiable patient information can only be accessed without consent by the direct care team for clinical care and service improvement. “Direct care team” is shorthand for “those who would have legitimate access to the data as part of their normal duties” and encompasses various members of clinical, administrative, information governance staff etc. If someone has that access as part of their NHS role, they can access the information to use for a study and need to ensure that use is in line with trust policies and procedures.

b) NHS staff would be able to anonymise the data. UWE staff not part of the direct care team, as per above definition, would not. UWE staff also working within a patient’s direct care team may know the identity of their study participants even if they anonymised the data. Knowing who the patients are is not an ethical issue as long as researchers consider whether they are following best research practice. Generally, the provision of anonymised data by someone from the direct care team to UWE staff outside of that direct care team for study purposes does not require patient consent. Identifiable patient information should never be transferred outside the NHS unless permitted by ethical review, and with patient consent.

c) Best practice is to obtain consent for the use of identifiable patient information. Where research and/or service evaluation is being conducted by UWE staff or students outside of the direct care team and identifiable patient information is required to recruit, access or acquire patient data, consent must be obtained. Account must also be taken of issues related to ‘power imbalance’ between clinician and patient. Acceptable options would be, for example:

- A clinician who is involved in the direct care team can explain the study during the consultation and hand out a Participant Information Sheet (PIS) with the study team contact details on and appropriate identifiers of the study sponsor(s) and ask the patient to contact the team directly.
- A clinician who is involved in the direct care team can use a ‘consent to contact’ form and if the patient doesn’t mind being contacted about the study, they can complete the consent to contact form for researchers to contact them directly.
- The study team could prepare a letter with the header from the clinic on it, and arrange with the clinic to send out letters and the PIS with the study team contact details on and appropriate identifiers of the study sponsor(s) to potentially eligible patients. Patients can be asked to contact the research team directly (or speak with their clinician if they are part of the research team). The clinic may require payment for this. The research team can save money and effort by joining in with appointment letters that the clinic were sending anyway.

  Therefore:

d) A UWE staff member or student conducting either research or evaluation (including all definitions of service evaluation) can access identifiable patient information **only** if they are part of the patient’s direct care team, and would legitimately have access to that information for research purposes. Otherwise, permissions for the UWE staff member or student to receive identifiable information must first be obtained by someone in the direct care team who would

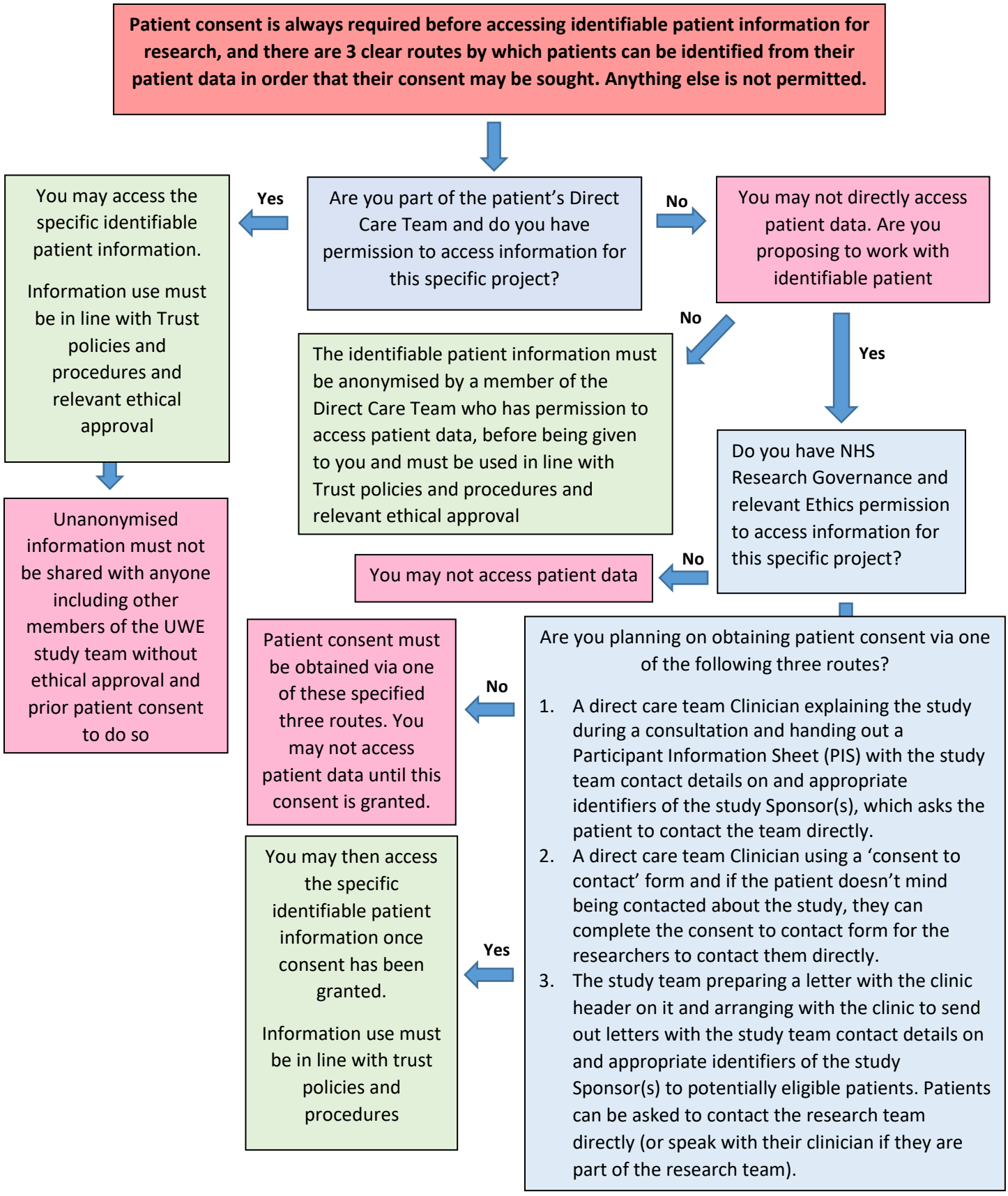
legitimately have access to that information in line with trust policies and procedures (e.g. permission from the Caldicott guardian), and/or by one of the acceptable methods outlined above.

e) Anonymised data can be given to a UWE staff member or student having first been anonymised by someone in the direct care team who can legitimately access that information.
f) Where a UWE researcher, staff or student, is part of the direct care team, and has legitimate access to the information, they must not share this unanonymised information with anyone, including other members of the UWE study team without ethical approval and prior patient consent to do so.

Further information about using patient data can be obtained from the Health Research Authority.
https://www.hra.nhs.uk/covid-19-research/guidance-using-patient-data/#guidance

Please refer to the flow diagram below. If you then still have queries that this guidance does not address, please contact the research ethics team (researchethics@uwe.ac.uk).

Flow Diagram for those wishing to access identifiable patient information for research



Version history

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Equality Analysis:	No issues have impacted on decisions of the Committee
First approved by:	RESC (final version by correspondence)
This version approved by:	RKEC/ 21 September 2022
Effective from:	December 2022
Next review date:	September 2024
Senior Policy Owner:	Professor John T. Hancock (Chair)
Policy Author:	Chair of RESC (JTH) and Research Governance Manager, RBI (RCR)
Overseeing committee:	Research and Knowledge Exchange Committee
Compliance measures:	Annual RESC Audit. FRECs report to RESC and Annual Assurance Reports go to RKEC. Any ethics breaches escalated as appropriate.
Related policies, procedures and codes of practice:	Other relevant Research Governance Policies including UWE Code of Good Research Conduct; Human Tissue Quality Management System; UWE Research Data Management Policy.
Related legislative and/or regulatory requirements	Data Protection and Health and Safety legislation. Legislation and regulation relating to all aspects of research with human participants, including, for example, legislation relating to Safeguarding of Children and vulnerable Adults, and legislative requirements of research in the NHS/Social Care; Mental Capacity Act; Prevent.