# UWE Bristol Handbook of Research Ethics

## Version 2.0 2 September 2024

Draft Version 2 [July 2024]. This Handbook replaces Version 1 of the Handbook, which replaced the previous RESC Policy and operating procedures, and separate guidance documents, which are now included in this handbook.

# Contents

# 1. Research Ethics Introduction

## 1.1 Introduction

1.1.1 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).

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

1.1.3 For undergraduate (UG) and postgraduate taught (PGT)/Master's 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 CRECs. 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 CRECs will be exceptional. See Section 2.5 below for more details.

1.1.4 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).

1.1.5 These procedures apply to all staff (including Emeritus or visiting colleagues) and students conducting or contributing to research which takes 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 Research Ethics Committee (REC). A favourable ethical opinion from another properly constituted REC can then be ratified by UWE (see Section 2.3 below).

1.1.6 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).

1.1.7 A full, unconditional favourable ethical opinion must always be in place before any activities which need it take place.

## 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.

Modern ethics would also add respect for human dignity which focusses on issues such as equality, inclusivity and diversity. More recently, it has also 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

1.4.1 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 1.5. 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.

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

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

1.4.4 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. This should be set within the context of the University's due diligence policies and procedures.

1.4.5 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.

1.4.6 **Security-sensitive research** must be submitted to the University Ethics and Integrity Committee (UEIC) for ethical review (see section 15 below).

1.4.7 **Secondary data** analysis requires ethical review except in the specific circumstances as detailed in section 1.5 below (see also section 7 below on secondary analysis).

1.4.8 **Social media data** analysis, even if anonymised and in the public domain, retains a risk that the data could be used to re-identify individuals, thus ethical review will be required (see section 13).

1.4.9 **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 CRECs, due to the nature of its business. The following detailed requirements/guidance relate specifically to UEIC and CRECs.

1.4.10 **Artificial Intelligence (AI):** Research involving novel or ethically sensitive research uses of AI requires ethical review. (UWE is developing its position in relation to AI in research, along with the rest of the sector.) AI clearly presents significant potential opportunity, but also risks, including ethical risks, and for this reason, ethical review is currently required. Please see also the currently available UWE guidance for using generative AI Principles for using generative artificial intelligence (AI) - Academic information | UWE Bristol.

### 1.5 Types of research not requiring ethical review

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

1.5.1 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.

1.5.2 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.

1.5.3 **Evidence synthesis** (including systematic reviews, realist reviews, meta-ethnography) of published literature.

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

## 2. University Ethics and Integrity Committee and College Research Ethics Committees

The University UEIC reports via the University Academic Board which is Chaired by the Vice-Chancellor of the University. Each College has a CREC, which is a sub-committee of the

College RKEC, though reporting on matters of ethical policy and process to UEIC. Collectively the UEIC and CRECs (along with AWESC) are referred to as University RECs. College Scrutineer Pools report to the CRECs and in particular the CREC Chair, and undertake the majority of ethics scrutineering activity. The roles and responsibilities of REC and Pool members are set out in **Annex 2.**

The terms of reference of UEIC and CRECs are available at the Committees and groups web pages.

## 2.1 Composition and membership

2.1.1 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.

2.1.2 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, and in line with the University's Conflicts of Interest policy.

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

2.4 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 CREC and UEIC membership, including the time of members to properly discharge their duties as scrutineers and as part of collegial decision making.

2.5 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.

## 2.2 Training

2.2.1 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 their 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.

2.2.3 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

2.3.1 A primary task of the RECs, supported by Scrutineer Pools, 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, research data security, and to the suitability and feasibility of the proposal.

2.3.2 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 secure 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
- any security sensitive or dual use considerations
- any environmental harms, such as habitat damage, or the inappropriate or wasteful use of resources
- AWESC will need to be assured in relation to animal welfare and ethics in relation to its business.

2.3.3 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.

2.3.4 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.

2.3.5 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), all of which must be in English, 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.

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

2.3.7 In the event that a CREC/AWESC finds itself unable to make a decision regarding a particular research proposal, the relevant Chair may, at any time, forward the research proposal to the UEIC for its consideration. This could be due, for example, to the complexity of the proposed research, or due to a split decision within the CREC. The CREC can refer cases to the UEIC that require advice or opinion. Referral to the UEIC for a review will be in exceptional circumstances only. The UEIC will not normally challenge CREC or AWESC decisions, as that is where the detailed expertise rests. Once a CREC 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 CREC.

## 2.4 Staff and PGR (doctoral) student ethics applications

2.4.1 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, all members will be asked to review applications, where the Chair determines a full committee review is necessary. This may take place 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.

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

2.4.3 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.

2.4.4 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.

2.4.5 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.

2.4.6 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.

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

2.4.8 Detailed information about how to apply is at **Annex 1**.

## 2.5 Undergraduate (UG) and PGT (Master's) student applications

2.5.1 All student research or individual projects with enquiry and/or analysis must be supervised and the Supervisor is responsible for the conduct of the research. Undergraduate (UG) and PGT (Master's) research projects carried out as part of taught modules including dissertations require ethical review in the first instance by the UWE Supervisor. The University approach to student research is proportionate to the level of study and the potential risks of doing the research.

2.5.2 The level of risk will usually be determined by the Supervisor completing the University's online Student Ethical Review Record for Taught Programmes. The Supervisor must complete this form (not the student) and this will determine whether, in the Supervisor's view, the research is high or low risk. Supervisors may give a favourable opinion to proceed to any project indicated to be low risk following completion of the Student Ethical Review Record.

2.5.3 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, and timings allow, the Supervisor may, working with the student, submit a full application to the relevant CREC. It is expected that most student research will be low risk, so the Supervisor should carefully consider whether the project can be amended such that it is low risk.

2.5.4 All UG and PGT student research, determined by this process to be high risk, must undergo full ethical review. The Supervisor will be asked to justify why this proposal is high risk. A full ethics application is needed which clearly discusses and addresses any ethical issues in order for it to be reviewed and approved. The Supervisor must make the application on behalf of the student. The Supervisor and student should retain a copy of the ethics application and

the favourable ethics opinion, and approval of any subsequent amendments, and the confirmation letter or email should also be included as an appendix to the dissertation.

2.5.5 In some cases, programmes may require UG or PGT/Master's 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 CREC unless the Student Ethical Review Record indicates that it is high risk, when the Supervisor should submit it on behalf of the student, as above.

## 2.6 Apprenticeship programmes

2.6.1 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.

2.6.2 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), and UWE online ethics training. 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.

2.6.3 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.

## 2.7 Monitoring, Auditing and Reporting

The UEIC and CRECs recognise that the definition and perceived significance of ethical problems may be subject to change and difference of opinion. In this light, the UEIC will conduct an annual review of its work reporting annually to Academic Board on the management of the Ethics Committees via an annual assurance report, indicating in particular any suggested or agreed change in policy or procedures. The UEIC will also report on any outstanding or anticipated difficulties. Each REC will provide a report to the UEIC 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 CREC annual report will also be presented to the appropriate College CRKEC for information.

The UEIC will carry out an annual audit on selected aspects of UEIC's and CRECs' 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. AWESC will undertake a separate audit, reporting to UEIC, with involvement from UEIC where appropriate.

# 3. Research in the NHS and social care

## 3.1 Specific requirements for ethical review for NHS research

3.1.1 When research is being carried out in the NHS with patients, their data or tissue, an 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 Master's level applications may be eligible (Master's students need to complete the Student Research Toolkit to check eligibility). Students working at undergraduate level are no longer accepted for NHS REC review.

3.1.2 Advice should be sought from the UWE Research Ethics team before applying, and the University will need to agree to be the research Sponsor, where that is required. 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.

3.1. 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 CREC for consideration by the Chair for formal ratification of the NHS REC decision (this consideration to take into account local UWE issues).

3.1.4 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.

3.1.5 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.

3.1.6 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.

## 3.2 Public Patient Involvement

A further requirement of research in the NHS relates to patient and public involvement (PPI).

3.2.1 PPI is the inclusion of patients and non-patients (potential patients, carers, supporters, people who use health and social care services, the general public) in designing, prioritising, conducting and disseminating health and social care research. It is defined by the NIHR as being done with or by patients and the public, not to, about or for them. It is about working collaboratively with patients and the public and sharing decision-making. Examples include:

- Being a member of an advisory group
- Co-applicant on a bid
- Reviewing ethics applications
- Helping to design interview schedules and surveys
- Helping to interpret data
- Helping to communicate findings to lay audiences

3.2.2 Some of the potential benefits of PPI for research include:

- Making the process and outcomes of research more relevant to the needs and preferences of patients and the public
- Improving the quality of research, for example, ensuring that the role of those people taking part in the research is clearly explained, the burden for these participants is reasonable, and recruitment strategies are effective
- Helping to ensure research outcomes are acceptable and appropriate for those intended to benefit from them
- Patients and the wider public can be involved at any stage in the research process.

3.2.3 Does patient and public involvement require ethical approval?

These activities are distinct from being involved in research as a participant or research subject. Research subjects/participants are protected by research ethics committees (REC) which review research proposals and protect the rights, safety, dignity and well-being of research participants. Formal ethical approval (i.e., via the Health Research Authority or University ethics committees) is not generally required for PPI activities as public contributors are members of the research team actively involved in decision making in research. They are not research participants.

Occasionally patients or members of the public may have direct access to study participants as part of their PPI roles. In these situations, ethics committee will wish to be reassured that the people undertaking these roles have had sufficient training and support to carry out this work. For more information see the statement from INVOLVE/NRES here: NIHR also provide resources for applicants to NIHR research programmes.

UWE therefore does **not** require PPI to have ethics approval **per se**, however, the involvement of PPI in research **should** be specified within the UWE research ethics application, such that the ethical issues related to the involvement of these individuals, as

part of the research team, can be considered alongside the rest of the application. One further specific, which will need to be included in ethics applications, relates to the HRA Participant Information Quality Standards. The HRA have also issued Participant Information and Design Principles, which make clear the requirement to involve public contributors in the design and review process of participant information to ensure it is relevant and understandable for the target audience.

3.2.4 What is the difference between PPI and qualitative research?

In health and social care research, it is often essential to understand the experiences and beliefs of patients, carers, the wider public, health professionals. Broadly, qualitative research refers to a wide range of methodologies which seek to address questions relating to "why?", "how?" and, "for whom?" Qualitative research aims to "study things in their natural settings, attempting to make sense of, or interpret, phenomena in terms of the meanings people bring to them"[1].

Qualitative research can help us to develop a better understanding or explanation of people's experience, e.g., exploring the beliefs, attitudes, or knowledge of patients or health professionals regarding a particular phenomenon or issue. It can be used to explain why or how quantitative investigations may have observed particular findings.

3.2.5 Comparing and contrasting PPI and qualitative research activities.

There are similarities in both the ways patient and public involvement (PPI) and qualitative research activities are conducted, and sometimes in the language used to describe them. Because of this, the distinction between the two can sometimes be blurred. These similarities can cause confusion for academics, public contributors and PPI leads but the intent of these activities is always different.

PPI aims to improve the design and conduct of research through the involvement of the public.

Qualitative research addresses research questions through the collection and formal analysis of non-numerical data from participants using predefined methodology.

In practice, what differentiates a PPI workshop from a qualitative research focus group may sometimes be unclear. The table below summarises key characteristics of both activities.

[1] Denzin and Lincoln 1994, p2

**Qualitative research and patient and public involvement in health and social care research: What are the key differences?**

This is a question we get asked all the time so we wanted to develop a simple answer. Drawing on great work from Canada [1] and on many helpful comments from reviewers, we have written a short list of what we see as the main differences between qualitative research and involvement. This table is more of a prompt to stimulate thought and discussion, rather than a definitive guide.

| | Qualitative research project | Involvement in a research project |
|---|---|---|
| **Research question** | Aims to answer a research question | Aims to help select and refine a research question |
| **Practical approach** | Follows a chosen method based on theory | Researchers and patients/public exchange views in a way that suits both |
| **People involved** | Seeks views from a defined sample | Seeks a range of perspectives from people with diverse experiences |
| **Ethical approval** | Requires ethical approval | Needs to reflect ethical practice but does not normally need ethical approval [2] |
| **People's input** | Seeks people's input as data to answer a research question | Seeks people's input to inform and influence decisions about how research is designed, undertaken and disseminated |
| **Power** | Only researchers have the power to make decisions about how the project is run | Patients, the public and researchers share power to make joint decisions about how the project is run, based on their combined views |
| **Use of findings** | Generates findings that may have wider application | Generates insight and learning that may be specific to the researchers and patients/public involved and their particular project |

**Bec Hanley, Kristina Staley, Derek Stewart, Rosemary Barber, August 2019**

**References**

[1] Doria et al. (2018) Sharpening the focus: differentiating between focus groups for patient engagement vs. qualitative research. Research Involvement and Engagement, 4:19. [2] Health Research Authority Best Practice Guidance on Public Involvement: (2019) www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/what-do-i-need-do/

### 3.2.6 PPI and participatory research

Participatory research is often considered a grey area where qualitative and PPI activities are often confused. Similarly, qualitative investigations may employ an emergent designs research. However, both of these would still be considered research rather than PPI and the methodology would be described in a protocol and subject to ethical review. PPI is still required to complement these approaches, for example when planning a particular event e.g., how and where an event should take place, who should be invited and so on.

## 3.3 Research Sponsorship

### 3.3.1 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.

### 3.3.2 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.

3.3.3 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.

3.3.4 If your project involves human participants who are NHS patients:

- You will need to apply for NHS REC ethics approval through IRAS. To do so, you will need sponsorship arrangements confirmed.
- If you are a member of staff, you will need to contact the CREC 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 CREC 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 CREC Officer.
- 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.
- If you require UWE Bristol to act as Sponsor, then you will need authorisation from the Dean of Research and Enterprise for this on your IRAS form. The CREC 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.
- If you are a student, you will first need your Supervisor to approve your IRAS application before approaching the CREC Officer or seeking authorisation from the College.
- 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.
- 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 CREC Officer.

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

- Familiarise yourself with the Procedures and guidance for human tissue research at UWE Bristol.

- 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.

# 4. Applying for Retrospective Ethical Approval

## 4.1 Process for applying for retrospective ethical approval

4.1.1 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 UEIC that there are exceptional circumstances for their failure before starting their research to obtain a favourable ethical opinion;

Step 2: The full UEIC, 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.

4.1.2 Applications must therefore be made to UEIC 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 UEIC will consider the reasons and decide whether it considers the circumstances to be exceptional. A record will be kept of decided cases by the UEIC. If the reasons are considered exceptional, and therefore the application can proceed to the second stage of the process, the full UEIC will vote on whether the application, as submitted to UEIC, could have been given a favourable opinion without conditions. If both conditions are satisfied, the UEIC may exercise its discretion to grant a favourable opinion for the research. UEIC may choose to seek expert Scrutiny from the relevant CREC, and advice from the relevant CREC Chair. When the full Committee agrees that the conditions for a favourable opinion can be met this decision may be approved by email.

4.1.3 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 approved, 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, including the protection of their data.

## 4.2 Decisions related to retrospective ethical approval

4.2.1 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.

4.2.2 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:

4.2.3 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 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 aspects) or other appropriate management action. But it 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.

4.2.4 For applications involving animals and animal by-products, AWESC will perform the role specified for UEIC, due to the specialist nature of the business, and Committee expertise.

# 5. Ethical Review Appeal Process

## 5.1 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.

## 5.2 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 UEIC unless the scrutinising committee was UEIC, in which case the matter should be raised formally with the Chair of Academic Board.
- 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.

## 5.3 Process for Investigating an Appeal (relating to both CRECs and AWESC)

- 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 UEIC who will make a decision. The UEIC Chair's decision cannot be further appealed. If the appeal is against a decision of UEIC, and the applicant remains unsatisfied, the appeal will be referred to the Chair of Academic Board, and in this case the Academic Board Chair's decision cannot be further appealed.
- Appeals and their outcomes will be reported to UEIC and the relevant CREC committees

## 6. 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.

## 7. 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. Approved UWE online survey platforms are available currently Microsoft Forms and Qualtrics (Online Forms and Survey Tools Intranet Guide), to UWE students and staff which enable 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).

## 7.1 Informed consent

7.1.1 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, those who are non-verbal, or who cannot read, or graphically represented for those with learning disabilities.

7.1.2 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 or conditions where individuals move in and out of capacity (see Mental Capacity Act 2005). It may be appropriate in such circumstances for an authorised person to give consent on the individual's behalf (where the MCA applies, there is clear guidance about what this means). 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. Although each case will be considered on its merits, this is unlikely to be appropriate for student research, and will always be regarded as high risk and requiring a full ethics application.

## 7.2 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. It is necessary, for reasons of audit and funder conditions, for the recipient of any payment, including vouchers, to be identified to UWE's

finance department, so ethically this must be made clear in advance to those who will receive them.

## 7.3 Confidentiality, anonymity and the limits of confidentiality

7.3.1 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.

7.3.2 It is critical to be clear whether data will be anonymised, or pseudonymised. Researchers cannot tell participants their data 'will be fully anonymised' where in fact they could still be re-identified (as is often the case when there is provision for participants to remove their data from the study, and the pseudonymisation code involves non-random information such as initial or gender). Not all data needs to be anonymised, but researchers must be clear about what is, or is not, the case. For example, following analysis, it may be the intention to completely anonymise data, and at that point identifiers may be fully removed, and that would be the point at which participants would understand that their data could no longer be removed from the study.

7.3.3 The Information Commissioners Office have issued Guidance on anonymisation which explains the difference between anonymisation and pseudonymisation as:

'Anonymisation means that individuals are not identifiable and cannot be reidentified by any means reasonably likely to be used (i.e., the risk of reidentification is sufficiently remote). Anonymous information is not personal data and data protection law does not apply.

Pseudonymisation means that individuals are not identifiable from the dataset itself, but can be identified by referring to other information held separately. Pseudonymous data is therefore still personal data and data protection law applies.'

7.3.4 But anonymising data is complex, and, for example in relation to small sample sizes, specific populations or rare medical conditions, it may still be possible to identify an individual from a dataset. Researchers must therefore inform themselves fully in order to handle the anonymity aspects of their research. The UK Data Service provide useful guidance about how to anonymise quantitative and qualitative data.

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

a) Precisely what is proposed in relation to their data, during the life course of the research
b) Any potential risks that might mean that the confidentiality or anonymity of personal information may not be guaranteed;
c) Which individuals and organisations, if any, will be permitted access to personal information, how that will be controlled, and under what circumstances such access will be permitted;

d) 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).

7.3.5 There are almost always some limits to confidentiality. Researchers should, when seeking consent, make clear the limits to confidentiality. For example, when focus group methodology is employed, there will be a limit to confidentiality, as the researcher cannot fully control this. It is also particularly the case when working with potentially vulnerable individuals or groups, such as 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. Aside from these exceptions, it must be clear to participants what the conditions of confidentiality are at all stages of the research, and researchers can only do what they have told their participants they will do in this regard.

## 7.4 Recording consent

7.4.1 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 one of the UWE approved online Survey platforms (currently Qualtrics and Microsoft Forms). Please see the University's Online Forms and Survey Tools Intranet Guide and use only approved platforms. For surveys, the consent form can form the first page of the survey instrument (as long as the participant information sheet is also available here to participants). For qualitative research, a hyperlink can be included in the invitation email and/or participant information sheet to a one page/one item Qualtrics or other UWE authorised consent form.

7.4.2 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.

7.4.3 For sensitive data, there is a greater the need for secure transport and a 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, including the Information Security Policies, the Research Data Management Policy and the Research Data Security Guidance, before coming to a decision about what is necessary and appropriate, and setting in place appropriate safeguards.

7.4.5 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.

## 7.5 Recording, storing and transcribing data online

7.5.1 Qualtrics and Microsoft Forms are currently the only UWE approved platforms for conducting online surveys. Qualtrics is currently freely available to all UWE staff (for research purposes) 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. It is important to note that the University is currently investigating an alternative to Qualtrics, so Qualtrics may not be available in the longer term. This Handbook will be updated when further information is available. Please refer to the Online Forms and Survey Tools intranet guidance.

7.5.2 Microsoft Teams is the approved UWE platform for qualitative research data collection online. This platform is 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.

7.5.3 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.

7.5.4 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 by default have access to the recording (until that access is removed by the researcher – advice on how to remove access is available from IT services).

7.5.5 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, encrypted recording device placed next to the computer, then immediately upload the recording to OneDrive and securely delete from the recording device).

7.5.6 We will continue to review this and may be in a position to revise this guidance if alternative capabilities become available.

7.5.7 OneDrive for Business version and Microsoft Teams are the only UWE-approved GDPR compliant and secure Cloud location for the storage of data. Do not use Google Drive, personal OneDrive, Drop-Box or other Cloud storage or software to store research data, as these are not secure. **In this context, it is critical to be aware that confidential data must not be entered into generative AI systems.**

7.5.8 If using Microsoft Teams for recording is not practical a UWE owned encrypted recording device must be used. Advice must be sought, beforehand, if for any reason an alternative is necessary. Students should seek advice from the Supervisors, and staff should seek advice from researchgovernance@uwe.ac.uk.

7.5.9 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 to which only the research team have access. 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 securely deleted from the recording device.

7.5.10 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.

7.5.11 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, information security and Data Protection risks. Seek advice from the Research Ethics Admin Team and/or IT before planning to use any non-approved platform for research (please note any systems or software must be purchased through ITS). For more information see the Research data security web pages.

# 8. Safeguarding vulnerable participants in research

## 8.1 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.

## 8.2 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)
- People recently displaced by conflict, or in conflict zones. Consider vulnerabilities also in terms of groups (e.g., asylum seekers), settings (e.g., rough sleeping) or timing (e.g. after bereavement).

## 8.3 What are the researchers' responsibilities 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

## 8.4 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

## 8.5 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 the participant to stop data collection (e.g. interview) easily, at any time.

Researchers need to be clear on:

- UWE and partner/ access 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

## 8.6 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.

## 8.7 UWE key links and resources

- If you are uncertain or want support in planning the safeguarding of vulnerable participants in your research, contact your College Research Ethics Committee (CREC) chair or the University Ethics and Integrity Committee (UEIC) chair via researchethics@uwe.ac.uk.
- 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

## 8.8 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'.

# 9. Evaluation and audit studies

## 9.1 What are evaluation and audit?

9.1.1 Evaluations generally seek to systematically assess the efficacy, efficiency or effects of a particular service or policy. There are different understandings (definitions?) 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.

9.1.2 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.

9.1.3 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.

9.1.4 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.

## 9.2 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.

## 9.3 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.

### 9.4 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.

### 9.5 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.

## 10. 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.

## 11. Secondary analysis of existing data

11.1 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.

11.2 Secondary analysis of previously collected data may be beneficial 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.

11.3 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.

11.4 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.

11.5 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.

## 12. 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.

## 13. Ethical issues in the use of social media in research

This guidance is designed to inform researchers about some of the potential ethical implications arising from the use of social media in research. A broad definition of social media is adopted here, 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.

## 13.1 Informed consent

13.1.1 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.

13.1.2 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.

13.1.3 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.

13.1.4 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*.

13.1.5 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.

13.1.6 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?

## 13.2 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).

## 13.3 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?

## 13.4 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?

### 13.5 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?

### 13.6 Selected national resources

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

UKRI/ESRC (2022) Internet mediated research

## 14. Power Dynamics in Research

As part of good ethical practice, it is essential that the design and conduct of the research takes into account the power dynamics between those involved in the research. The critical requirement here is that the power dynamics involved should not interfere with fully informed consent, including the right not to participate, or to cease to participate, being in place. The British Psychological Society Code of Ethics puts it this way:

'Investigators should realise that they are often in a position of real or perceived authority or influence over participants. For example, they may be gathering data from their students, employees or clients, from prisoners or from other detained or vulnerable people. This relationship must not be allowed to exert pressure on people to take part in or remain in an investigation and the potential for a power relationship to bias the data should be considered. Similarly, where people in positions of power over potential participants, for example, school teachers, managers or prison staff, serve as gatekeepers or recruiters for research, the potential for coercion arising from the power relationships should be recognised and steps taken to avoid it.'

Examples of situations where issues of power dynamics may occur are set out below.

## 14.1 Research where there are 'gatekeepers', such as prison authorities, school teachers, social workers.

In such instances, it is critical that the power relationships between the gatekeeper and participant is not such that undue influence would be brought to bear. This might involve fear of reprisals, or even simply unwillingness to disappoint or desire to please. This must be fully considered, and mitigations articulated in the research ethics application. It is also critical that fully informed consent is taken, and evidenced – this is the job of the research team, not the Gatekeeper (the Researchers, not the Gatekeepers, need to be in a position to defend that this actually took place). For example, researchers, rather than teachers, must assure that parental consent is in place, even if teachers make the initial approach, and in addition that there is consent, or at the least assent (and where appropriate continuous assent), from the child.

## 14.2 Researching within one's own organisation

14.2.1 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.

- **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.

In these circumstances, it is vital that individuals have the right not to participate. They need not to fear repercussions in the workplace, so this is especially important in relation to senior staff researchers. There should also not be undue 'peer pressure' where 'everyone is taking part', and an individual finds it difficult to say no. In this context, the position of the researcher in terms of power dynamics is relevant – for example an external university researcher, or an internal member of staff, potentially in a senior role. It will often be inappropriate for a senior manager within an organisation to conduct research involving the participation of staff who report to them. Where a case can be made that this is ethically appropriate, it will usually be the case that consent is taken independently 'at arm's length' from the researcher, and in such a way that refusal to participate is a tenable option for the individual.

- **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 as they may feel unable to decline the request to participate due to concerns of repercussions in the workplace, for example that it may adversely impact management perceptions of their commitment and thus their careers. There may also (perhaps for this reason) be undue peer pressure, with everyone 'being seen to take part'. 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.

  Fully informed consent from individuals must, however, always be in place, and their wellbeing protected. 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 a UWE approved online Survey tool rather than in person. Where research methodology is, for example, observational, as may be the case in ethnographic or participatory research, it is insufficient to simply have the consent of the organisation concerned, or a manager (that would be necessary, but not sufficient). The method of consenting must also be appropriate to the research, for example continuous consent throughout the project, where the research engagement is lengthy. Where the research changes, for example where a grounded theory approach is taken, then further ethical review may be necessary dependent on what was originally approved and the nature of the change. Guidelines are available, such as from the Association of Social Anthropologists and the British Psychological Association, as well as other disciplinary Learned Societies, in relation to best ethical practice, including both consent and confidentiality. The HRA have produced guidance related to consent within the NHS, a setting where there may be obvious power dynamics at play between doctor and patient, or Doctors and more junior staff, and a clear need for fully informed consent.

- **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. In these circumstances it may be necessary to get consent for each specific quote to be used rather than the usual 'blanket consent' to use any direct quotes.

14.2.2 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. In cases where mitigations do not provide sufficient assurance in relation to the risk of power dynamics being inappropriately at play in relation

to initial approach, consent, and effective anonymisation (where that is promised) are unlikely to be granted a favourable opinion. The REC will also take into account the experience of the researcher. Where this is student research, and where the issues of power dynamics remain a significant concern even once mitigations have been considered, and the learning objective could be achieved by, say, researching in an alternative setting, then this is likely to be regarded as a more appropriate way forward. Each case will be considered on its own merits, and the REC will wish to see evidence of full engagement with the issues by the DoS/Supervisor.

### 14.3 Reference

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

## 15. 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.

### 15.1 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;
- UEIC 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 UEIC from the CRECs;
- Once identified the Chair of UEIC will notify UWE Bristol's Prevent Lead of the project. If provided, comment from the Prevent Lead will be taken into account by UEIC 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.

## 15.2 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.

## 15.3 How does UEIC manage security sensitive research applications & protect researchers?

15.3.1 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.

15.3.2 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 CRECs identified as involving security sensitive research will be referred to UEIC, either by self-notification by the applicant or by identification during scrutiny. Once referred to UEIC the application will be scrutinised in the usual way and a decision will be made by UEIC Chair's Action. If approved, UEIC will be asked to ratify the decision at the next quarterly UEIC meeting.

15.3.3 In the case of a project identified as involving security sensitive research the UEIC 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 UEIC'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.

15.3.4 As part of UEIC'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 UEIC 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:

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

15.3.5 UEIC 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.

## 15.4 Application procedure for security sensitive research projects

15.4.1 For staff and postgraduate research students:

- Applications for ethical approval for potentially security sensitive projects should be made by the usual processes;
- If a researcher indicates that security sensitive research is being undertaken on the application, then the application should be sent for approval to UEIC, rather than the relevant CREC.
- If a researcher does not indicate that the project involves security sensitive research the application will be forwarded by the CRECs to UEIC for scrutiny;
- UEIC scrutiny and Chair's Action will be undertaken in the usual way;
- The Chair of UEIC 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;
- A record of the project will also be held by the research ethics administration team in RBI on their secure database.
- 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.

15.4.2 For taught students (PGT and UG)

- As a general principle UEIC 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.
- 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, for example, intending to visit extremist websites or speak to individuals of concern, then it should be considered as potentially security sensitive.
- 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 UEIC that projects in category 2) will be extremely rare.
- 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 UEIC.
- 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.
- The Chair of UEIC 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.
- A record of the project will also be held by the research ethics administration team in RBI on their secure database.
- 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.

## 15.5 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 CREC Chair for advice or contact the UEIC Chair via: researchethics@uwe.ac.uk.

# 16. Autoethnography

## 16.1 Introduction and UWE Context

Autoethnography is an orientation to scholarship, often presented as a research method, that is thriving in many disciplines (i.e., Business and Organisational Studies, Sociology, Cultural Studies, Education, Gender and Queer Studies etc). There are numerous definitions

of autoethnography, one such is from the American Psychological Association 'Essentials of Autoethnography', 2021(here):

'Autoethnography is an autobiographical genre of academic writing that draws on and analyses or interprets the lived experience of the author and connects researcher insights to self-identity, cultural rules and resources, communication practices, traditions, premises, symbols, rules, shared meanings, emotions, values, and larger social, cultural, and political issues.'

Autoethnography uses personal experiences, recollections, diary entries, fiction, poetry film and other cultural artefacts to explore a topic affectively as well as intellectually. As such, autoethnographic projects might not pose clear research questions but should declare the area(s) that are being explored alongside any associated literatures.

Examples include:

- A doctoral thesis that explores the therapeutic qualities in the art of drag.
- A project that researches into deep music listening, transcendental meditation, therapeutic qualities, and Persian culture.
- A project that offers a reflexive and critical account of 'remodelling Barbie' workshops.
- A project where a parent considers their own parenting experience.

## 16.2 Practical considerations

Autoethnography is known for its attention to relational ethics. Issues such as informed consent, confidentiality of material obtained during the research process, and anonymity need room for both intellectual and relational consideration. Part of these considerations will include applying for CREC approval for the project. Researchers employing this technique should note:

- Relational ethics rest on continuous and complicated **judgement calls**. The ubiquitous 'do no harm' applies here as anywhere else.
- **Supervisor – Supervisee relationship** is key so that relational ethics (among other things) can be sufficiently discussed.
- **Continuous consent** might be required if engaging with, and writing explicitly about, others. Whilst it may seem illogical to produce a Participant Information Sheet for one's self, the researcher will need the consent of those who may be impacted by any aspect of the project.
- Difficult conversations with others which take place as part of the research but which had not been anticipated at the outset might require **additional ethical scrutiny** after original ethical approval has been obtained.
- There is a strong recommendation to read the literature around **relational ethics** – the key issue that must be wrestled with is how to treat knowledge that occurs in an interaction/relational context.
- What to call the people on the periphery of the project is an issue of ongoing debate in the literature. The format that has been opted for in some projects is to call them **'cultural members'** (e.g. drag artists) or **'co-travellers'** (i.e. people travelling through life and looking for creative outlets).
- **Self-care and harm to the researcher, and others involved,** is paramount. Researchers should therefore pay particular attention to what activities might be undertaken and how

they might impact the researcher and those around them. Where individuals who may be involved are children, or vulnerable adults, special care must be taken. Issues around consent (especially if the researcher would normally be the consenting adult), and, for children in particular, potential future harm or future desire to withdraw from the study, must be carefully considered (such as considerations around the use of visual images or otherwise identifiable data, see also ICO Guidance on the right to erasure).

Further guidance can be sought from the College Research Ethics Committee by emailing researchethics@uwe.ac.uk.

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

## 17.1 Do only what your favourable opinion covers you to do

- You may 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.

## 17.2 Make sure you have appropriate collaboration agreements in place

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. If there may be intellectual property elements to your research, this will need to be included in any agreements as relevant. For more information see the Intellectual property web pages.

## 17.3 Research Governance Record (RGR)

All staff and doctoral research must be entered on the UWE Research Governance Record. This is a mandatory requirement. You should enter your UWE Ethics approval number on the RGR as soon as you have it. (see links CHSS CATE CBL)

## 17.4 Research Data Management Plans

A UWE research data management plan is a 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, processed, analysed, 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). This is critical for legal compliance, and it protects you should anything go wrong. It is mandatory for staff and doctoral research. It is recommended a proportionate RGR should be in place for student research, to ensure that any research data involved will be appropriately managed, and disposed of.

## 17.5 Health and Safety Risk Assessments

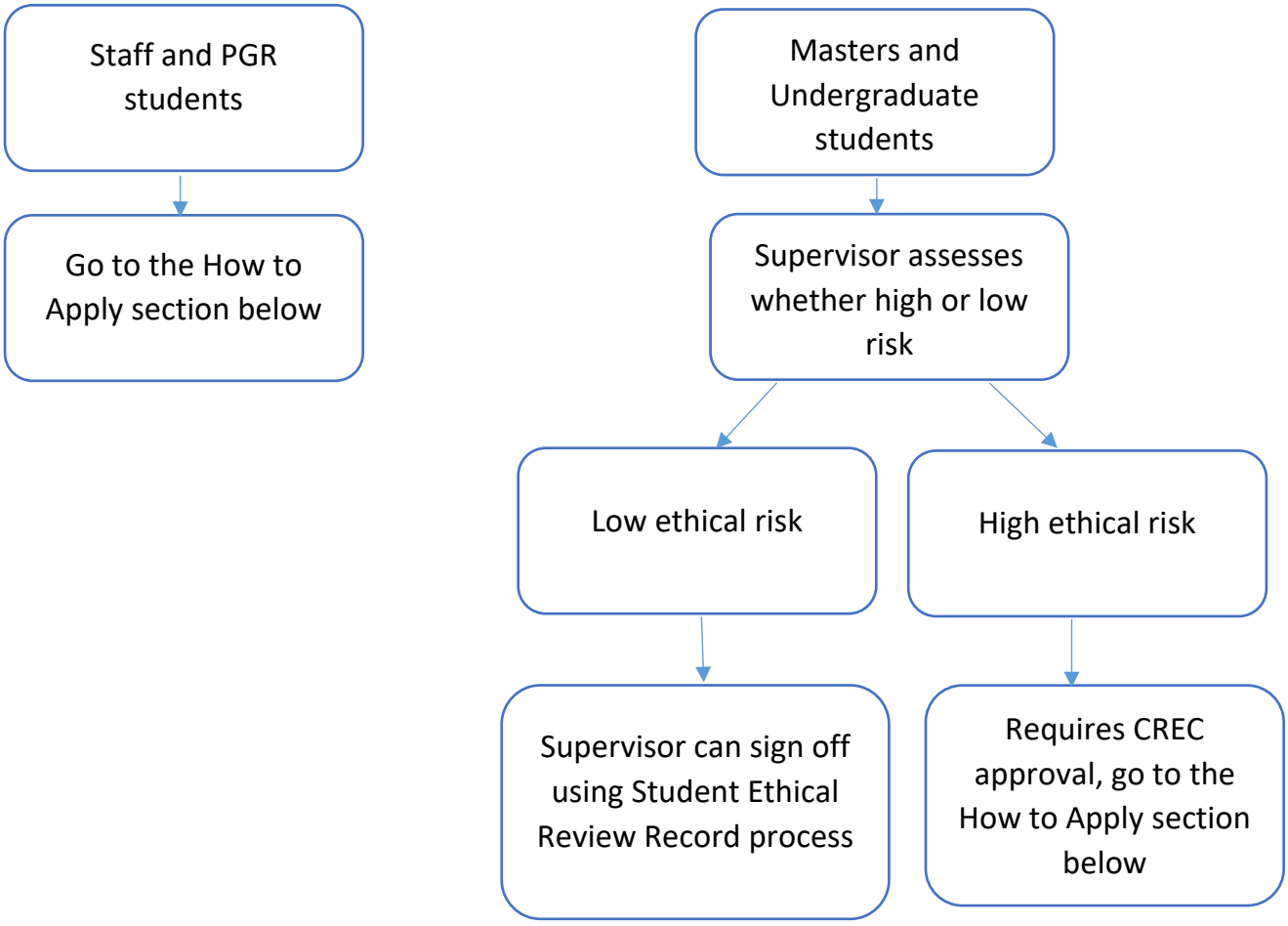
Risk assessment is a required process of identifying the hazards present in the workplace or in work activities, and evaluating the extent of the risk involved. Its purpose is to either eliminate the risk of injury or to reduce the risk of injury to a safe level. It is an absolute requirement that where the activities involve risks greater than in everyday life, an appropriately endorsed risk assessment should be in place. This should be attached to your RGR, for staff and doctoral research.

## 17.6 UWE Research Governance Requirements

Please consult the UWE Code of Good Research Conduct which sets out the University's requirements and expectations of researchers.

# 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**

**Guidance about how to apply can be found here.** *Please note that the guidance currently at this link relates to the current system of ethics application and review. UWE will be moving to a Worktribe based ethics system this year (Summer 2024). As soon as that is in place, the guidance at this link will be amended. Please note that the new Worktribe based system will incorporate applications for work involving humans, animals and animal by-products and other elements of ethical risk including environmental risks.*

**What documentation do you need to provide?**

For applications involving human participants you are required to provide the following details (as applicable to your research):

- Research proposal or project design
- Participant information sheet(s) and consent form(s)
- 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. You should also allow for time to resolve any queries.

**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, 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 may be given feedback to help you to improve your application, either as conditions of approval, or feedback that Scrutineers consider you may find helpful (and it will be clear which this is). 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 or use your data in ways not specified in your consent form, you can't do it! So always be careful to scope in advance of submitting your application everything you propose to do.

**Are you GDPR compliant?**

- Templates for participant information sheets, consent forms and a privacy notice for staff and postgraduate research (PGR) students are available **here**. These are Data Protection legislation compliant and should be used.
- Undergraduate and postgraduate taught (Master's) 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. See also the Data Protection guidance for UWE Bristol students.
- For staff and Doctoral researchers, participant information sheets, consent forms and other relevant documentation must include the UWE Bristol logo (see UWE Bristol logo usage). For taught programme students, this should not be used, unless the University has specifically and explicitly agreed to be the Data Controller for the research (in most instances this will not be the case.

**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 ratification for this from UWE. At present you should email this to researchethics@uwe.ac.uk. When the new Worktribe ethics system is in place, ratification will be done as part of this online system.

**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. When the new Worktribe ethics system is in place, amendments will be done as part of this online system.

**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.

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 UEIC/CREC 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, or this would unacceptably delay other applications already in the system.

Annex 2

# CREC Chairs' top tips for getting your ethics application approved quickly

Applications for ethics review are often delayed due to incomplete or inconsistent documentation. We asked our CREC 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(s), participation sheet(s), privacy notice(s), 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. **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).
5. **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)
6. **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).
7. **Make sure that all forms of participant recruitment and are included and explained in your description of the methods** 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.
8. **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?
9. **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.

10. **Do you need assistance?** If in doubt seek assistance from the relevant CREC 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 does not 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 was 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

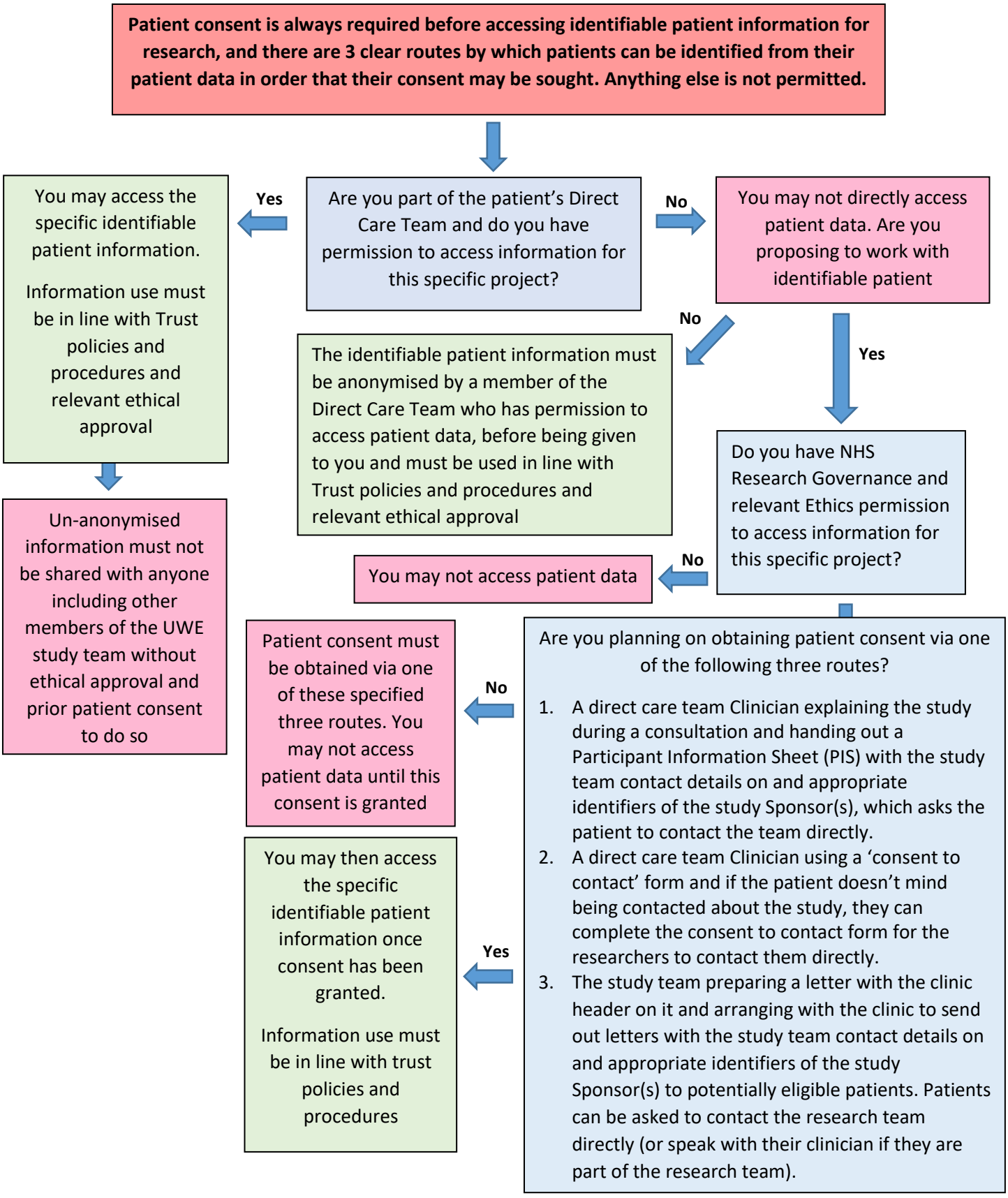
legitimately have access to that information in line with trust policies and procedures (e.g., permission from the Caldicott guardian), and/or by one of the acceptable methods outlined above.

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 un-anonymised 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



# Annex 4

## Responsibilities of College Research Ethics Committee (CREC) and College Pool members

**Responsibilities of College Ethics Committee (CREC) Members**

1. Attend CREC meetings.
2. Leading by example, promote a culture of research excellence within the College and assist in disseminating good practice around research ethics and raising awareness and understanding of UWE Ethics policy and procedures.
3. Act as a contact person for staff and students seeking advice on research ethics within the School/College.
4. Support PGR research supervisors as appropriate and provide advice on research ethics to module leaders delivering research training
5. Contribute to the development of Research Ethics Guidance.
6. Complete and refresh relevant UWE Mandatory training including Research ethics, Research Data Management, Safeguarding, Information Security, Data Protection and Health and Safety.
7. Attend and take part in UEIC ethics training and any UEIC led ethics cross committee meetings.
8. Contribute expertise on specialist areas of research relevant to the College or School.
9. Take part in the scrutiny of applications and consider any ethics applications referred for full Committee discussion as a result of Scrutiny.
10. Scrutinise any applications referred by UEIC for specialist scrutiny.
11. Provide input in relation to applications for retrospective approval made to UEIC.
12. Report at CREC meetings any School concerns, queries or suggestions relating to research ethics policy and procedures.
13. Assist in the routine monitoring of research activity within the College (as it relates to ethical practice) and contribute to UEIC audit activities as requested.
14. Observe strict confidentiality in relation to all Committee business, including in relation to individual applications.
15. Be cognisant of the work of other Committees, including the Animal Welfare and Ethics Sub-Committee, Human Tissue Sub-Committee and the Biological Safety Sub-Committee.
16. Be cognisant of the underpinning legislative and regulatory framework within which the University operates, as relevant to research, including due diligence, data protection and health and safety.
17. Raise any relevant concerns or issues with the CREC Chair.

**Responsibilities of College Scrutineering Pool Members**

1. Receive ethics applications for scrutiny and complete and submit scrutineer reports to an acceptable quality, complying with scrutineer guidelines, and within agreed timescales.
2. Respond in a timely manner if it is not possible to scrutinise an application which has been allocated (so that it can be allocated to another scrutineer without delay).
3. Complete and refresh relevant UWE Mandatory training including Research ethics, Research Data Management, Safeguarding, Information Security, Data Protection and Health and Safety.
4. Keep updated on research governance policies and procedures at UWE.
5. Keep updated on related policies and procedures, such as information security, data protection, safeguarding, disclosure and barring, health and safety as they apply to research.
6. Undertake and keep up to date UWE Scrutineer Training.
7. Inform the research ethics team of any periods of leave or other lack of availability for scrutineering sufficiently far in advance as to permit efficient planning.
8. Provide expert scrutiny in relation to any applications referred from UEIC, where appropriate.
9. To observe strict confidentiality in relation to individual applications and any other matters which require confidentiality.
10. Be cognisant of the underpinning legislative and regulatory framework within which the University operates, as relevant to research, including due diligence, data protection and health and safety.
11. Raise any relevant concerns or issues with the CREC Chair.

## Version history

| | |
|---|---|
| Document name: | UWE Bristol Handbook of Research Ethics |
| Version number: | V 2.0 |
| Equality Analysis: | No issues have impacted on decisions of the Committee |
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| Senior Policy Owner: | Professor John T. Hancock (Chair) |
| Policy Author: | Chair of UEIC (JTH) and Research Governance Manager, RBI (RCR) |
| Overseeing committee: | University Ethics and Integrity Committee (UEIC) |
| Compliance measures: | Annual UEIC Audit. CRECs report to UEIC and Annual Assurance Reports go to Academic Board. 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; AWESC 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; Human Tissue; Prevent. |