THE UNIVERSITY OF SHEFFIELD

ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS PERSONAL DATA AND HUMAN TISSUE:
GENERAL PRINCIPLES AND STATEMENTS

1 FUNDAMENTAL PRINCIPLES OF RESEARCH ETHICS

The founding motto of the University of Sheffield is 'To discover the causes of things'. The University's vision includes producing the highest quality research to drive intellectual advances and address global challenges, delivering the highest standards and best practice in research integrity and ethics.

The paramount principle governing all University of Sheffield research involving human participants, personal data and human tissue is respect for the participants' dignity, rights, safety and well-being.

1.1 Participants' rights

Participants have a right, as a principle of research ethics, to:

- be fully informed about how and why their data will be collected and used as part of a research project, and by whom;
- consent to participate, withdraw from, or refuse to take part in research projects;
- confidentiality: meaning that personal information or identifiable data should not be disclosed without participants' consent;
- security of their data: meaning that data and samples collected should be kept secure and anonymised where appropriate;
- safety: meaning that participants should not be exposed to unnecessary or disproportionate levels of risk, and;
- request that their data be deleted if and when it is no longer required for research purposes.

1.2 Researchers' obligations

Researchers have an obligation to ensure that their research is conducted with:

- honesty;
- integrity;
- minimal risk to participants and to themselves; and
- respect for other people, their values and their cultures.

Guidance on the interpretation and application of these principles is detailed in this Policy document.

These principles of research ethics are recognised in international and regional treaties, as well as national laws. Breach of these principles may, in some instances, be a civil or criminal offence. The principles and requirements outlined in this Policy reflect the principles of research ethics but do not displace a researcher's obligation to comply with any relevant legal and regulatory requirements.

Ethical research conduct does not require the avoidance of potentially high-risk research. Rather, an ethical approach to research involves proper recognition of, and preparation for,

risks, and their responsible management. Ethical research is therefore a matter of being risk aware, not risk averse.

Finally, if research ethics are to be more than merely formulaic and procedural they must be meaningful and relevant to - and accepted by - researchers. To this end, this Policy specifies an ethics review procedure that is devolved to academic departments in the first instance, and which depends on ethically aware, self-reflective researchers taking responsibility for operationalising the principles and requirements embodied in the Policy.

2 SCOPE OF THIS POLICY

The University of Sheffield's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue applies only to research involving human participants, personal data and human tissue. What is understood by the terms 'human participants', 'personal data' and 'human tissue' is discussed in Research Ethics Policy Note no. 1. It does not cover broader ethics or integrity issues that may apply to any type of research (e.g. ethical issues surrounding the source of funding for research), or ethical issues surrounding the use of animals in research.

For the purposes of various statutory returns (such as those to the Higher Education Statistics Agency) the University is required to define research in line with the conventions set out in the Frascati Manual, which is the internationally recognised methodology for collecting and using research and development (R&D) statistics.

Research must be "creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge."

This work must be novel, creative, uncertain, systematic, transferrable or reproducible.

For the purposes of this Policy, the definition of research includes work of educational value designed to improve understanding of the research process. However, the definition of research excludes:

- the routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques;
- internal audits, service evaluations or reviews, within the management procedures of organisations (except where there is an intention for the findings of such work to be disseminated as research and/or in fulfilment of a student research assignment);
- 'Public and Patient Involvement (PPI)' or 'Public and Patient Involvement and Engagement (PPIE)', in which patients or members of the public are involved in contributing to how research is designed, conducted and disseminated (except where there is an intention for the findings of such work to be disseminated as research and/or in fulfilment of a student research assignment); and
- the development of teaching materials that do not embody original research.

Information about the re-use of existing data in research (e.g. data collected for a non-research purpose such as audit, service evaluation or PPI) can be found in Research Ethics Policy Note no. 13.

3 RESEARCH ETHICS AT THE UNIVERSITY OF SHEFFIELD

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue recognises that the responsibility for maintaining ethical conduct lies, in the first instance, with researchers themselves. If researchers do not take responsibility for the ethical conduct of their own research, defensible research ethics will not be possible. To this end, responsibility for operating the University's Ethics Review Procedure, informed by the Policy, is devolved to academic departments and funding units.

Within this devolved framework, the University recognises that diversity enriches and strengthens its research culture and performance. Diversity means that research activities involving human participants, personal data and human tissue may differ widely from one department or funding unit to another. Thus, the ethical issues relating to human participation in research may also differ considerably from one academic department or funding unit to another.

The key principle underlying the Research Ethics Approval Procedure is that researchers should reflect on the ethical issues that are raised by their research and be able to justify, in ethical terms, the practices and procedures that they intend to adopt during their research. Matters of research ethics are often not 'black and white', and there is no 'one size fits all approach'. This Policy therefore aims to set a clear framework and guiding principles to assist researchers in addressing the ethical issues that may arise in the course of their research.

4 RESEARCH GOVERNANCE AND RESPONSIBILITIES

Heads of departments and funding units are responsible for the conduct of the research that is undertaken in their departments. They are therefore responsible for ensuring that researchers within their respective departments and funding units have access to appropriate ethics review procedures for research activities that involve human participants, personal data or human tissue, in line with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue. They are also responsible for ensuring that all research-active staff and students are familiar with the content of the Policy and that appropriate training and guidance is made available. In particular, it is compulsory for all staff to undertake the University's Information Security training, and this training is also recommended for students who undertake research involving human participants, personal data or human tissue. Researchers wishing to submit a University ethics application *must* successfully complete three online Information Security courses provided by the University (Protecting Information; Protecting Personal Data; and Protecting Research Data) before they can access the application form. As in all other matters, individual researchers are expected to follow the leadership of their Head of Department.

In everyday research practice the primary responsibility for considering, respecting and safeguarding the dignity, rights, safety and well-being of human participants and those whose data or tissue are used for research, lies with the lead researcher (e.g. the principal investigator or supervisor). However, this practical principle does not absolve more junior, or

more senior, staff, or students, from personal responsibility in this respect, or from their responsibility to disclose any failure to meet the principles of conduct required by the Policy.

All researchers at the University of Sheffield, whether staff members or students, are responsible to a range of stakeholders for their conduct during, and delivery of, their research activities involving human participants, personal data and human tissue. These are:

- the human participants involved (as defined by this Policy), including those identified as potential participants;
- those whose data or tissue are used within the research;
- others who may come into contact with the research activities;
- society in general;
- the University of Sheffield;
- fellow researchers, whether colleagues or students;
- colleagues who undertake research support activities;
- their department or funding unit;
- the research funder; and
- their academic profession or discipline.

The University Research Ethics Committee (UREC) is responsible to the University's Senate for:

- reviewing the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue every 5 years and reporting its findings to the University's Senate;
- offering guidance within the University on the interpretation of the Policy;
- resolving disputed or uncertain ethics approval decisions;
- auditing and accrediting the ethics review arrangements in place within departments and funding units on at least a 5 yearly basis, and monitoring the ethics review arrangements within departments and funding units;
- in the event of concerns arising about whether a research proposal or ongoing research activity complies with the Policy, suspending the approval process, or the research activity in question, pending further investigation;
- actively promoting awareness and knowledge of the Policy, and research ethics more generally, within the University via training events and other activities;
- keeping abreast of externally-driven developments, policies and regulations concerning research ethics, and ensuring that the University meets all necessary requirements;
- providing advice on any ethical matters relating to research that are referred to UREC from within the University.

5 SCOPE AND APPLICABILITY OF THE RESEARCH ETHICS POLICY

The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue applies to:

- all University staff (including emeritus, honorary and visiting staff*), and registered students who conduct, or contribute to, research activities involving human participants, personal data or human tissue, whether these take place within or outside University premises and facilities, or are part of a work placement undertaken in fulfilment of a University degree award; and

- all individuals who conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises, facilities and/or systems.

This includes research undertaken by non-academic departments of the University of Sheffield, and administrative research undertaken within academic departments or faculties. For further definition and discussion of these activities and the procedures for their ethical review, see Research Ethics Policy Note no. 7, 'Administrative research within the University'.

* For emeritus, honorary and visiting staff this relates to research undertaken as part of their work for the University of Sheffield (i.e. where their association to the University would be included in any publication/dissemination of the research findings). If University of Sheffield ethics approval is required, the application should be made by a full staff member who is collaborating on the work, naming the emeritus/honorary/visiting staff member as co-applicant.

The University of Sheffield's Policy is designed to complement the National Health Service (NHS) ethics review system and does not, therefore, duplicate the functions, or overlap with the remit, of the NHS ethics review system. For further detail about ethics review via the NHS ethics review system, and information about which University research requires NHS, rather than University, ethics approval, see Research Ethics Policy Note no. 5.

Other external bodies, such as some public-sector social care providers or the armed forces, also have their own research ethics policies and review procedures. In the case of social care research, see Research Policy Note no. 5. In all other cases, contact the Secretary of the University Research Ethics Committee for guidance.

Research funding bodies may have their own research ethics policies and/or requirements, which must be met as a condition for receiving research funding. However, this does not obviate the need for observance of the University's Policy and its associated procedures; in such cases, the external policies and requirements are an *extra* layer of research ethics governance, not an alternative to the University's Policy.

Similarly, external research collaborators may be required to follow the ethics policies and procedures of their own organisations. However, the University's Policy and procedures must still be followed in any collaborative research that involves University of Sheffield staff or students. In some cases, an external organisation's ethics review procedure may be deemed sufficiently robust that additional ethical approval via the University of Sheffield's procedure is not required – see section 4 of the Research Ethics Approval Procedure for more details ('Alternative Ethics Review Procedure').

The final external stakeholders to be considered are professional bodies and learned societies, which may also have their own research ethics policies, guidelines and requirements. While learned societies' research ethics guidelines are useful resources that may offer supplementary guidance, the University's Policy must, in the first instance, take precedence for University staff members and with respect to research conducted on University premises. Although it is unlikely that professional ethical codes will conflict with the University's Policy, in the event of a perceived conflict of this kind, the member of staff concerned should contact the Secretary of the University Research Ethics Committee for guidance.

6 THE OBJECTIVES OF THE ETHICS POLICY GOVERNING RESEARCH INVOLVING HUMAN PARTICIPANTS, PERSONAL DATA AND HUMAN TISSUE

The Policy is intended to:

- protect the dignity, rights, safety and well-being of human participants;
- codify the University's position on research ethics for research involving human participants, personal data and human tissue;
- demonstrate a commitment to high quality, transparent and accountable research ethics throughout the University;
- warrant and inform the operation of the University's Ethics Review Procedure within departments and funding units;
- provide guidance on research ethics involving human participants, personal data and human tissue for all staff and students;
- encourage an organisational research culture based upon defensible standards of research practice;
- reduce risks to the University, departments and funding units, and individual researchers;
- strengthen the eligibility and quality of University research funding applications; and, not least,
- enhance the University's reputation with the general public and wider society, within the academic professions, and with funding bodies and external auditors.

7 GOOD RESEARCH PRACTICE

Observing recognised research ethics principles is basic to good research practice in general. The University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue should, therefore, be read alongside:

- the University's Good Research & Innovation Practices (GRIP) Policy;
- the University's Preventing Harm in Research & Innovation (Safeguarding) Policy; and
- the University's Research Misconduct Toolkit.

Upholding ethical standards in the conduct of research means accepting and respecting principles of integrity, honesty and openness. Conducting research with integrity means embracing intellectual honesty and accepting personal responsibility for one's own actions.

Prior to, during, and following the completion of research activities, researchers are expected to consider the ethical implications of their research and, depending on its nature, the cultural, economic, psychological, physiological, political, religious, spiritual and social consequences of the research for the human participants involved.

Researchers should always consider their research from the perspective(s) of the participants and any other people who may possibly be affected by it.

8 SAFETY AND WELL-BEING

Finally, issues of safety and well-being are at the heart of research ethics. Researchers have a responsibility to protect all participants, including those identified as potential participants,

and those whose data or tissue are used in the research, as well as they can, from avoidable harm arising from their research.

As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those they encounter in their normal lifestyles. If it is expected that harm, unusual discomfort or other negative consequences might occur during or after participation in a research project, the researcher should highlight this during the ethics approval process, and discuss the matter fully with participants during negotiations about informed consent.

Researchers also have a responsibility to consider their own safety and that of any co-researchers or collaborators. Additionally, the University's Preventing Harm in Research & Innovation (Safeguarding) policy extends this responsibility further, to considering the potential for harm to others who may come into contact with the research activities. For example, this may include family members, members of households, or members of a local community who may be present during the research activities, or with whom members of the
research team or participants may come into contact during fieldwork. All those involved in or potentially affected by a research project should be informed of appropriate routes for reporting safeguarding concerns.

However, it should also be noted that it may not be possible for researchers to identify every eventuality that may arise in the course of a research project, and that this Policy is not designed to cover all possible situations. Unexpected incidents affecting the safety or well-being of those involved, and/or presenting a potential reputational risk to the University, may arise even in a project that has been well-considered and thoroughly ethically reviewed. Should such an incident arise, the researcher should take appropriate steps to manage the immediate situation in line with the University's Preventing Harm in Research & Innovation (Safeguarding) policy and Health and Safety procedures. At the earliest opportunity they should make their supervisor or line manager aware of the situation. Where there are potential implications relating to research ethics (e.g. if the terms of ethics approval have been breached), the UREC's Secretary should be contacted for advice.

Further detailed discussion of informed consent, and safety and well-being, can be found in Research Ethics Policy Notes nos. 2 and 3.

THE UNIVERSITY OF SHEFFIELD

RESEARCH ETHICS APPROVAL PROCEDURE

1 INTRODUCTION

The University's approach to research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed, and research ethics approval obtained, before data gathering commences *unless* an appropriate exemption applies (see section 1.1 below).

This approach applies to all university staff (including emeritus, honorary and visiting staff) and registered students who conduct, or contribute to, research activities involving human participants, personal data or human tissue, whether these take place within or outside University premises and facilities. This includes administrative research undertaken by or on behalf of academic or non-academic departments/faculties of the University of Sheffield. It also includes collaborative projects that involve one or more colleague(s) from other organisations (in which case negotiations regarding the design of the project should incorporate agreement with respect to how and where appropriate ethics approval will be obtained).

Staff and students can seek ethics approval for their research project(s) via a number of possible routes, which are outlined in Section 2 of this Policy document.

In addition, all individuals who, although they are not members of the University, conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises and facilities are expected to:

1. Provide evidence of appropriate ethics approval (from an ethics review process that is sufficiently robust in comparison to the University's Research Ethics Policy and Research Ethics Approval Procedure – see below),

2. Obtain appropriate permission(s) from the relevant area(s) of the University (e.g. Head of Department). The appropriate person(s) would need to be provided with details of the aims of the research, who the target participants would be and what the research itself would involve so that they can make an informed decision about whether the research should proceed.

The University Research Ethics Committee (UREC) is able to offer support in assessing whether an external ethics review process is sufficiently robust. Enquiries should be directed in the first instance to the UREC's Minute Secretary.

The definition of research is outlined in the General Principles and Statements section of this Policy. The definition of a human participant is outlined in Research Ethics Policy Note no. 1.

Researchers have a duty of care towards all individuals whom their research may affect, not just those who are directly involved as participants; the potential for harm or distress to any such individuals should be considered at the outset, and appropriate steps taken to mitigate this risk where necessary. Further detailed discussion of safety and well-being can be found in the Preventing Harm in Research & Innovation (Safeguarding) Policy, and Research Ethics Policy Note no. 3.

It is an expectation that research undergoes a process of academic or scientific review and approval prior to submitting for ethics approval, to ensure that the methods and proposed purpose of the research are robust and appropriate.

This is partly to enable the ethics reviewers to focus on the ethical issues rather than, for example, the design and methodology. This will also help to ensure that research is of a sufficiently high quality, and to avoid a situation in which it might be deemed unethical to involve participants because the research is not of sufficient value/merit.

Academic or scientific review can be internal or external. Internally, this would typically be conducted at departmental level within the University of Sheffield, and all departments define their own processes. Different methods of academic review are used across the University; amongst others, these include assessment of a research proposal by module leader or dissertation supervisor, feedback on research proposal from a supervisor, a departmental confirmation review process, or a process to facilitate discussion of, and feedback on, a research proposal from colleagues, Head of Department or Director of Research. Externally, research funders also undertake academic review of research proposals as part of their processes for processing grant applications. If a project has been awarded research funding, then it can be assumed that it has received an appropriate level of academic review.

Research involving human participants, human tissue or personal data should not begin before research ethics review has taken place and ethics approval granted (unless an appropriate exemption applies). Retrospective ethics review is not permitted. It is the responsibility of the principal investigator or, in the case of a student project, the supervisor, to ensure that ethics review is undertaken in good time. There are no exceptions to this principle.

However, there may be circumstances in which there is legitimate uncertainty about when research begins (or has begun). In particular, materials may originally be noted without any explicit intention to undertake research, but subsequently become of research interest (i.e. they could be used as data within research). For more detailed discussion of the kinds of circumstances in which this may happen, and how the ethical approval for such situations may be dealt with, see Research Ethics Policy Note no. 10.

1.1 When is research ethics approval NOT required?

For the purposes of the University's Research Ethics Policy, ethics approval is not required in the following situations (for research involving external organisations/taking place outside the UK, researchers should ensure that they check whether the external organisation or other country has its own policies with respect to ethical review):

- The project is not research, under the definition provided in the 'General Principles and Statements' section of this Policy;
- The project does not involve human participants, either directly (e.g. through use of interviews, questionnaires, observation or other primary data collection methods) or indirectly (e.g. through provision of, or access to, personal data or tissue material). This includes:
    - A project which will only use publicly available anonymised data, such as census, population or other official statistical data;
    - A project which will only use existing clinical or research data that has been robustly anonymised such that it no longer constitutes personal data (i.e. the original providers of the data cannot be identified by the Data Controller using

either the dataset itself, or any other dataset that is either held by, or is likely to come into the possession of, the Data Controller). In such cases, the researcher should carefully consider the new research purpose in terms of whether it is likely to cause offence to those who originally provided the data (or other relevant groups of individuals), and should be confident that this would not be likely. Researchers are encouraged to use the self-declaration process available via the online Ethics Application System, to ensure that they have addressed all relevant considerations in using existing data as part of their project, and to ensure that this process has been appropriately documented.

- The project involves only published digital or print media (such as news reports or magazine articles) or public broadcasts, where the publication/broadcast has specifically been made available by an organisation for public consumption and there is therefore a reasonable assumption that the report may be used for research purposes. If there is any doubt regarding whether a publication/broadcast to be used for the research has specifically been made available by an organisation for public consumption, then ethics approval should be sought. It should be noted that research involving the use of comments made on such publications/broadcasts by individuals would require ethics approval, and that research involving social media, including blog posts, would also require ethics approval.
- The project involves accessing data from a publicly accessible archive or a formally constituted repository accessible to scholars, UNLESS the archive/repository requires ethics approval to be obtained. See Research Ethics Policy Note no. 9 'Archival Research' for further details.

In relation to the final two points, it should be noted that although ethics approval may not be required, any personal data collected and used as part of the research must be handled in line with relevant data protection legislation. For further information see Research Ethics Policy Note no. 4 'Principles of Anonymity, Confidentiality and Data Protection', and the University's Data Protection Policy and Information Security guidance.

Note regarding the Data Controller: according to the Data Protection Act, the Data Controller will usually be the University of Sheffield (i.e. not a particular individual or research team), although collaboration with other institutions may result in joint Data Controllers. In practice, in the case of discrete research projects, it is highly unlikely that members of a research team will come into contact with data from other parts of the University that may result in the re-identification of participants whose data has been anonymised. However, researchers should think carefully about this possibility when seeking to anonymise their data; strictly speaking, if there is any possibility that anonymised data could be traced back to the individual that provided it via any other data held by, or likely to come into the possession of, the Data Controller, then the data has in fact only been 'pseudonymised'. This means that it would in fact still be classed as personal data. Two examples of situations in which this problem is more likely to arise include:

- administrative research, in which research staff may have access to central University records that may link data to the participants that provided it;
- types of research which there are particular identifiers that are widely used outside the research team (e.g. health research involving NHS numbers).

1.2 Procedure to be followed in the event of concerns arising about whether a research proposal or ongoing research activity complies with the University's Ethics

Should concerns arise, for whatever reasons, about whether a research proposal or ongoing research activity complies with the University's Research Ethics Policy the UREC should be notified as soon as possible. The UREC will contact the Head of the Department concerned, as the person ultimately responsible for the implementation and observance of the Policy within that Department, indicating that the research activity in question, or the approval process with respect to the proposal in question, should be suspended in order to allow an investigation of the case. The UREC and the Department in question should carry out any such investigation collaboratively and as a matter of urgency. The UREC will determine the outcome of the investigation; the University's Policy on Investigating and Responding to Allegations of Research Misconduct, and/or another appropriate University procedure, may be activated (further details are set out in the University's Good Research & Innovation Practices policy).

In the case of students who have not obtained the appropriate ethics approval for their project, the Senate-approved '*Procedure for dealing with students who have not obtained research ethics approval'* should be followed (see section 1.2.1 below).

Should a member of staff or a student have concerns about whether a particular project is being managed ethically they should, in the first instance, report this to their Head of Department. The Chair or Secretary of the University Research Ethics Committee should be informed and the matter investigated fully in accordance with the process set out above.

1.2.1 Procedure for dealing with students who have not obtained research ethics approval

General University Regulation 10 states that:
"A person seeking to undertake research which would involve human participants, personal data or human tissue must comply with the University's Research Ethics Policy and, prior to the commencement of the research, must ensure that appropriate ethics approval has been obtained. Any breach of this Regulation may be dealt with under the Regulations as to the Discipline of Students."

Existing procedures require students and supervisors to be aware of the requirements of research ethics and their responsibilities in this area. All first year PGR students take a compulsory faculty-level DDP module on ethics and integrity, and many PGT/UG students in disciplines where research is likely to require ethical review also cover ethics as part of their research methods training. Supervisors, however, are ultimately responsible for ensuring students are aware of the need to obtain ethical approval where appropriate. As a final check in the case of PGR students, the 12-month confirmation review requires supervisory teams to declare whether ethics approval is required and if it has been obtained.

If a breach does however occur, it should be dealt with on a case by case basis, in particular taking into account what was known by the student and at what time. Their potential vulnerability and the role of their supervisor should also be considered. This does not negate the requirement that all researchers are expected to be familiar with the ethics review procedure and that they have received appropriate training. Any action taken against the student by a department should be proportionate to the circumstances, taking account of their explanation of events and any mitigating circumstances.

Where a student has not obtained ethics approval for a research project, the following procedure should be followed:

i. Any ongoing research on the project is halted with immediate effect on the instruction of the Head of Department;
ii. The Head of Department informs the UREC as soon as the incident is discovered, seeking advice and support as to the most appropriate way of conducting the investigation;
iii. The student and supervisor(s) should be informed of the department's concerns as soon as possible. They should be given at least three days' notice of any investigative meetings to be held and be informed that they may bring a friend or representative to that meeting;
iv. The department investigates and reports its findings to the UREC, together with recommendations for action. The recommendations relate to the specific case and, where appropriate, broader prevention strategies. The recommendations might include formally referring the case to the Student Conduct & Appeals Office for action under the Discipline Regulations;
v. If no formal referral is to be made to the Student Conduct & Appeals Office, a sub-group of the UREC, usually involving the Chair or Deputy Chair, the Secretary, and other appropriate members of the Committee if deemed necessary, considers the report and decides the final outcome, as well as agreeing what advice and support would be appropriate to offer the Department; the UREC may consult with Student Conduct & Appeals Office where necessary.
vi. The UREC communicates the final decision and outcome of the incident to the Department, along with any action that needs to be taken (for example, by considering any implications for the assessment process), and any agreed advice and/or offer of support.
vii. The Department reports back to the UREC to confirm when the necessary action(s) have been taken;
viii. The investigation, review and agreement on action all take place in a timely manner, as agreed between the Head of Department and the UREC and, where relevant, the Student Conduct & Appeals Office.

2 ROUTES FOR OBTAINING ETHICS APPROVAL

The lead researcher (e.g. the principal investigator or supervisor) is responsible for deciding whether ethics approval is required, and which ethics review procedure is applicable. Ethics approval can be obtained via four standard routes, which are outlined in this section.

It should be noted that for certain types of research there are specific legal, regulatory and governance requirements that must be considered alongside the requirements for ethical review (e.g. requirements that apply to health and social care research, human tissue research, and clinical trials of Investigational Medicinal Products or Medical Devices); further information is provided in Research Ethics Policy Note nos. 1, 5 and 10.

There is a legal requirement for research involving adults lacking in mental capacity to be reviewed by a recognised Appropriate Body under the Mental Capacity Act 2005. All NHS research ethics committees are Appropriate Bodies (see section 2.2). For further information, refer to Research Ethics Policy Note no. 5 and the Specialist Research Ethics

Guidance Paper entitled 'Research involving adult participants who lack the capacity to consent'.

In general, researchers working with external organisations, or working outside the UK, to carry out research should always check whether the external organisation or other country has its own policies with respect to ethical review, and should ensure that appropriate ethics approval is obtained via at least one of the following routes.

For research involving only existing (secondary) data, a questionnaire is provided via the University's Ethics Application System to help researchers establish whether ethics approval is required or not. This self-declaration process enables a researcher to obtain a letter confirming that they have been through a process of ethical assessment, providing their answers to the questions indicate that ethics approval is not required for their research.

2.1 The University Ethics Review Procedure (University Procedure)

This applies to research which:

- comes under the broad definition of research outlined in the General Principles and Statements section of this policy';
- does not require ethical review via an NHS Research Ethics Committee;
- is led by the University of Sheffield (unless there is no appropriate alternative procedure for ethical review (see section 2.3 below); and
- is undertaken in the United Kingdom or abroad, unless there is an appropriate alternative procedure for ethical review (see section 2.3 below).

For further information regarding the University Procedure, refer to Section 3 of this Policy document.

2.2 Review by a National Health Service Research Ethics Committee (NHS REC)

Review by an NHS REC forms part of the Health Research Authority's HRA Approval process. In general, review by an NHS REC will be required for research that involves participants identified in the context of, or in connection with, their use of NHS or adult social care services, and/or the relatives of such patients. There are also specific types of health or social care research that will require review by an NHS REC (e.g. a clinical trial of an Investigational Medicinal Product and some research involving the collection of human tissue). Research involving only the premises and/or staff of the NHS or adult social care services does not require review by an NHS REC. Researchers should refer to the HRA's ethics decision tool for full details:
http://www.hra-decisiontools.org.uk/ethics/

It should be noted that the definition of research applied by the NHS is not as broad as the definition applied by the University. Hence a project that does not need to be ethically approved by an NHS REC may still come under the remit of the University Procedure (e.g. a project that is defined as service evaluation within the NHS, but which is being undertaken as part of the research element of a University degree award, or for which there is an intention to publish the findings).

For further guidance on the NHS Ethics Review Procedure, please refer to Research Ethics Policy Note no. 5.

2.3 The Alternative Ethics Review Procedure

This applies to research for which ethics approval will be/has been obtained via another organisation's ethics review procedure (i.e. not via the University Procedure nor via an NHS Research Ethics Committee)This may include:

- research involving University of Sheffield staff or students which is conducted outside the United Kingdom;
- collaborative research involving one or more other universities or other organisations (which may be conducted either within or outside the United Kingdom);
- research being undertaken by a researcher who joins the University of Sheffield from another institution, where ethics approval was obtained via that institution prior to their transfer.

For further information regarding the Alternative Ethics Review Procedure, refer to Section 4 of this Policy document.

2.4 The Administrative Research Ethics Review Procedure

This applies to all administrative research (i.e. research which does not form part of the standard academic research that is undertaken within departments and research disciplines). It may be undertaken by, or on behalf of, professional service departments, or the professional service functions within academic departments or faculties. For further definition and discussion of these activities and the procedures for their ethical review, see Research Ethics Policy Note no. 7, 'Administrative research within the University'.

3 THE UNIVERSITY ETHICS REVIEW PROCEDURE (UNIVERSITY PROCEDURE)

The University Procedure has been designed to take into account the differences between disciplines, and aims to achieve an appropriate balance between carrying out the ethical review of research projects in a sufficiently rigorous way to effectively protect the welfare, dignity and rights of human participants, whilst also being risk-aware, flexible and as user-friendly as possible in order to facilitate research within departments.

The University Procedure is based on the following guiding standards:

- Quality: competent and consistent decision-making by ethics reviewers within, and across, departments should be enabled and encouraged.
- Effectiveness: the dignity, rights, safety and well-being of participants and researchers must be protected.
- Devolution: applications should be reviewed at department level, enabling researchers to 'own' their own research ethics, thereby raising awareness and allowing research to be reviewed by those with close knowledge of the particular ethical challenges raised by their departments' research activities.
- Flexibility: departments should, within the minimum requirements set by the University Research Ethics Committee (UREC), be able to tailor the procedure to fit their particular needs in a number of ways, such as enabling ethics reviewers to undertake the reviewing process individually via the online ethics system, or at a face-to-face committee meeting; being able to invite additional ethics reviewers to be involved where an application presents particular risks or challenges; or by creating discipline-specific guidance.
- Ease of application: the procedure is designed to be as simple and prompt as possible, while maintaining high standards. For example, when successive cohorts of undergraduate or postgraduate-taught students are required to undertake

sufficiently similar research projects, a single 'generic' research ethics application can be submitted.
- Efficiency: on average, departments should provide a decision on an ethics application within 10 working days.
- Independence: ethics reviewers must not have *any* conflict of interest with respect to an application they review (other than in the case of undergraduate or postgraduate-taught student research, for which the supervisor may be a reviewer).
- Proportionality: the detail and depth of the ethics review of any particular project should be in proportion to the estimated level of risk posed to prospective participants. This is not a straightforward matter; where possible researchers should take into account potential participants' likely perceptions of risk.
- Transparency: applicants should receive sufficiently detailed, critical and constructive feedback from reviewers to explain the decision made; this should also be able to satisfy the requirements of external scrutiny, if ever required.

Although ethics approval is required before any data collection involving human participants commences, applicants are expected to consider the ethical implications of their research at all stages of the project. Even the most well thought-out project may come across unexpected ethical challenges after approval has been obtained, and researchers should constantly reflect on the ethics of their research. If changes are made to the project after approval has been obtained, it may be necessary to obtain re-approval in certain circumstances, which are explained in Section 3.1.9 of this Policy document.

The University has an online Ethics Application System which facilitates the ethics review process, and all academic and professional services departments are expected to use this for the processing of ethics applications. However, since individual departments have some flexibility in how they operate the University Procedure, applicants are encouraged to refer to their own department for details before applying. The following section outlines the minimum requirements set by the UREC, within which departments must operate the procedure.

If changes need to be made to the project after approval has been obtained, refer to section 3.1.9 of this Policy document.

Under normal circumstances, research ethics applications, supporting documents and review decisions will be automatically retained within the online Ethics Application System and may be used for audit purposes.

3.1 The University Procedure in practice

3.1.1 When do I need to apply for ethics approval via the University Procedure?

University ethics approval should be sought if your project:

- is research as set out in the General Principles and Statements section of this Policy;
- involves human participants, personal data and/or human tissue (*unless* one of the exceptions outlined in section 1.1 applies)
- does not require ethical review via an NHS Research Ethics Committee;
- is led by the University of Sheffield (unless there is no appropriate alternative process for obtaining ethics approval – see section 2.3); and
- is undertaken in the United Kingdom or abroad (unless there is an appropriate alternative process for obtaining ethics approval – see section 2.3).

3.1.2 Who conducts the ethical review of research at the University?

Each academic department administers the University Procedure and grants ethics approval for research undertaken by its own researchers. Each department has one or more designated Ethics Administrators who are responsible for the administration of the procedure on a day-to-day basis, and a pool of ethics reviewers who conduct the ethical review of research projects submitted to the department.

Any University member of staff may become an ethics reviewer (with the approval of their Head of Department). Departments should ensure that staff appointed as ethics reviewers (including as supervisors of Undergraduate and Postgraduate Taught student research projects) receive appropriate training and/or guidance to help them fulfil this role effectively and that appropriate records of relevant training are maintained (for example via a training log for each reviewer/supervisor, maintained by the Ethics Administrator).

All ethics reviewers (including those who have undertaken ethical review for another organisation but who are new to the University of Sheffield) should have read the University's *Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue*. In addition, they should undertake at least one, and ideally more, of the following:

- attend one of the UREC's regular workshops for ethics reviewers; OR a department-run equivalent (departments are encouraged to use the training materials from UREC workshops as a basis for delivering their own internal training sessions);
- read/view the key resources for ethics reviewers provided on the central ethics web pages, including the recordings/slides of presentations delivered at ethics reviewer workshops, and the quick reference guide for reviewers, available here;
- read one or more of the training examples of ethics applications with reviewer comments, available here;
- shadow an experienced colleague whilst they ethically review one or more applications.

It is strongly recommended that only experienced reviewers are appointed to act as the lead reviewer. Reviewers should be encouraged to undertake refresher training from time to time, using any of the routes described above. They should also ensure they are aware of changes to the University's Ethics Policy and Ethics Review Procedure by reading email updates and bulletins circulated by their departmental Principal Ethics Contact and by the UREC.

Each department should also have a group of at least three ethics reviewers, constituting an Ethics Review Panel or Research Committee, who will be available to review contentious applications (i.e. where there is a significant, fundamental difference of opinion between the original ethics reviewers about the ethical implications of the proposed research); none of the members of the Ethics Review Panel or Research Committee should have a conflict of interest with the project in question.

Each department also has its own designated Principal Ethics Contact, who will normally communicate any changes in, or information relating to, the University Procedure to staff and students in the department. This person may also be the Ethics Administrator. The names of Ethics Administrators and Principal Ethics Contacts can be found here:

It is important that staff involved in supporting the ethical review process receive appropriate recognition for the work they undertake. Departments should ensure that their

workload allocation modelling accounts for the time taken by Principal Ethics Contacts, Ethics Administrators and reviewers in the discharge of their duties.

Sometimes, due to the requirements of a funding body or any other external body the cooperation of which is necessary for the research to proceed, lay input into ethical scrutiny will be required. In such cases, ethical scrutiny of research projects will be undertaken by a sub-committee of the UREC (see section 3.1.6 for more details).

N.B. The arrangements for the ethical review of administrative research are set out in Research Ethics Policy Note no.7: 'Administrative research within the University'. If a research project requiring ethical review will be carried out by part of the University that does not fall within the designated procedures for either academic or administrative research, the project leader should contact the Secretary of the UREC for advice on how to seek ethical approval.

3.1.3 How is a research project submitted for ethical review via the University Procedure?

The researcher completes and submits the online ethics application form (the Ethics Application System is accessed through 'My Services', and further details on how to submit an application can be found here):

The full application form cannot be accessed unless the researcher has completed three compulsory online Information Security courses within the time periods set by the University (courses not yet completed or requiring re-completion by the researcher will be indicated in the 'new application' screen):

- Protecting Information
- Protecting Personal Data
- Protecting Research Data

When submitting an application on behalf of others (e.g. a project team or a generic application covering a group of students) the applicant should ensure that all colleagues/students covered by the application have completed the necessary training, but evidence of completion does not need to be uploaded to the application for every person.

The application form should be accompanied by any relevant documentation. For example, if it is intended to use an information sheet, covering letter or written script to inform prospective participants about the proposed research, or if a consent form will be used to record participants' consent to participation in the research, these should form part of the application. The UREC provides guidance on preparing participant information sheets and consent forms. If participant documentation is to be provided to participants in a language other than English, English versions should be provided with the ethics application, and the researcher should arrange for these to be translated into relevant languages following confirmation of ethics approval.

Applicants should also provide further information such as the interview schedules, questionnaires or other research tools that they plan to use, if these are available at the time of review; departments are encouraged to adopt this as best practice, with recognition of the fact that it may not always be possible. Ethics reviewers may ask for subsequent sight of these, if they are not available at the time of applying. Further guidance from the UREC on the inclusion of data collection tools within ethics applications is available here.

Ethics reviewers should consider all supporting documents that have been provided by the applicant as part of their review of the application.

An application for ethics approval of a research project may only be submitted via one academic department. If a project involves staff from more than one department, one department must be selected as the channel through which ethics approval will be sought; the application cannot subsequently be submitted for ethics review in another department.

In some types of research, such as those involving participatory methods, or large projects with a number of work packages, it may be necessary/beneficial to submit a number of separate ethics applications for the same project over time. In such cases, the researcher should provide the reference numbers of any previously approved applications for the same project in response to the question 'Please enter details of any similar applications'. This ensures that the reviewers are aware that the application builds on a previous application, and can seek details of that application where needed. Departments may find it helpful to appoint the same reviewers to applications which are linked in this way, where possible.

3.1.4 Undergraduate and postgraduate-taught student research

Although the quality of ethics reviewing must be maintained for all types of research, some departments deal with very large volumes of research ethics applications from undergraduate and postgraduate-taught students. Since this can be a significant administrative burden, appropriate versions of the basic procedure have been developed for supervised undergraduate and postgraduate-taught student research, in two respects:

3.1.4.1 Distinct research projects: Where an undergraduate or postgraduate-taught student requires ethics approval for an individual research project that is distinct from any other student research, the supervisor is responsible for classifying the research as either 'low risk' or 'potentially high risk' (on risk assessment, see Section 3.1.4). A reduced number of ethics reviewers is required to review such projects, dependent on the risk level posed (for full details see Section 3.1.6).

3.1.4.2 Generic research projects: Where a number of undergraduate or postgraduate-taught students will be conducting research that is of a sufficiently similar nature to be reviewed together, a single generic ethics application can be submitted for review, using one application form. This process is designed to increase the efficiency of the University Procedure where departments may otherwise have to process large numbers of ethics applications for cohorts of students who undertake similar research projects each year. A generic research ethics review covers more than one sufficiently similar research project. There are two types of generic research ethics review:

Type 1, in which, at a particular stage in their course, a cohort of students undertakes the same research exercise involving human participants. These research projects are training exercises as part of an educational programme. Examples might be learning how to administer a particular psychological test or how to carry out specific laboratory procedures.

Type 2, in which students undertake slightly different research projects, which are sufficiently similar in terms of the following set of parameters to allow for generic research ethics review:

- the selected research topic;

- the chosen questions, aims and objectives;
- the chosen research methods and procedures;
- the type of human participant;
- the nature of the human participation;
- the type of method chosen to inform participants;
- the content of the information sheet, covering letter or written script; and
- the content of the consent form, where relevant.

An example might be a cohort of students that has to undertake questionnaire-based surveys to find out about adults' eating preferences or the relationship between smoking and health.

In the above cases, the person with primary responsibility for the research projects in question should submit a 'generic' research ethics application (e.g. a supervisor, a course leader, a research director, etc.). The University's standard online application form for staff includes a tick box for the applicant to indicate when their application is a 'generic research application'. The completed application should demonstrate that the request for generic research ethics review covers research projects that are sufficiently similar in terms of the parameters outlined above.

Despite the above, supervisors, course leaders or research directors responsible for generic research projects may, for educational and training purposes, decide to ask students to complete individual ethics applications, even though such applications do not necessarily require individual ethics approval via the Ethics Application System

Where a research activity that has been granted generic research ethics approval is repeated with different cohorts of students on a year-on-year basis, the academic staff member responsible for the activity should *review* the approval every year, to ensure that the activity in question has not changed sufficiently to render the original approval inapplicable. This annual review process, and the decision reached, should be documented. If there has been significant change, a new generic ethics application should be submitted. If there has not, a generic ethics approval should, anyway, be *renewed* every three years, i.e. a new generic ethics application should be submitted for review.

3.1.5 Assessing ethical risk

The UREC has developed broad definitions of categories of ethical risk. Research that is potentially *high risk* will involve 'particularly vulnerable participants' - whether directly, or in terms of personal data about them - and/or address 'highly sensitive topics'. Conversely, *low risk* research will involve neither 'particularly vulnerable participants' nor 'highly sensitive topics'. The third criterion that should be used to assess ethical risk is the nature of the research itself, particularly with respect to the safety and well-being of participants (including researchers); for example, any research that involves active intervention in the lives of research participants is likely to be more risky than a project that does not, and should be assessed accordingly.

The category of 'potentially particularly vulnerable participants' includes, but is not restricted to, the following.

(a) People whose competence to exercise informed consent is in doubt, such as:

- infants and children under 18 years of age;

- people who lack mental capacity, may be at risk of losing capacity or have fluctuating capacity; for example people with learning disabilities, people with dementia or conditions that give rise to cognitive impairments such as stroke;
- people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate; and
- people who may have only a basic or elementary knowledge of the language in which the research is being conducted.

(b) People who may socially not be in a position to exercise unfettered informed consent, such as:

- people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees);
- family members of the researcher(s); and
- in general, people who appear to feel they have no real choice on whether or not to participate.

(c) People whose circumstances may unduly influence their decisions to consent, such as:

- people with disabilities;
- people who are frail or in poor health;
- elderly people;
- people who are in care;
- relatives and friends of participants considered to be vulnerable;
- people who feel that participation will result in access to better treatment and/or support for them or others;
- people who anticipate any other perceived benefits of participation; and
- people who, by participating in research, can obtain perceived and/or actual benefits to which they otherwise would not have access e.g. possibility of a new medication being available, payment for participation.

For further discussion of research ethics issues with respect to the participation of vulnerable people, see Research Ethics Policy Notes nos. 2 and 6.

Potentially highly sensitive topics include:

- 'race' or ethnicity;
- political opinion;
- trade union membership;
- religious, spiritual or other beliefs;
- physical or mental health conditions;
- sex life, sexuality and/or gender identity;
- identity of an individual resulting from processing of genetic or biometric data;
- abuse (child, adult);
- nudity and the body;
- criminal or illegal activities;
- political asylum;
- conflict situations;
- personal violence;
- terrorism or violent extremism; and

- personal finances.

A key word qualifying all of the above lists is 'potentially'. It should never simply be assumed that the above kinds of research participants and topics are under all circumstances 'vulnerable' or 'risky': an unreflective 'box ticking' approach in this respect is strongly discouraged. In the first place, researchers should reflect upon the specificities of each research project, and the risks and vulnerabilities it may, or may not, present or create should be documented and evaluated as part of the ethics review process. In the second, departments are encouraged to develop local definitions of risk and vulnerability that are appropriate to the nature of their particular research activities, providing these definitions are endorsed by the UREC.

Finally, it cannot be emphasised too strongly that conducting research ethically is not a matter of avoiding potentially high-risk research. It is, rather, about preparing for and managing risks; it is a matter of being risk aware, not risk averse.

3.1.6 How is the ethical review of a project carried out via the University Procedure?
Once an application for the ethical review of a research project has been submitted via the online Ethics Application System, a notification will be sent to the appropriate person asking them to take action:

- For staff applications, this will be the departmental Ethics Administrator, who will then assign appropriate reviewers as per the minimum requirements set out below;
- For students at all levels, this will initially be the supervisor named in the application, enabling them to check that they are satisfied that the application is of an appropriate standard to be submitted for ethical review. Following the supervisor check, applications from postgraduate research students will be submitted to the departmental Ethics Administrator, who will assign appropriate reviewers; for undergraduate and postgraduate taught student applications, the supervisor will be asked to assess whether the project is low risk, or potentially high risk. Low risk applications may be reviewed by the supervisor themselves (unless individual departments have introduced their own policy which does not allow this), and potentially high risk applications will be sent to the departmental Ethics Administrator to appoint appropriate reviewers, as per the minimum requirements set out below.

Where more than one reviewer is required, a lead ethics reviewer will be appointed by the Ethics Administrator, to consider the decision and comments made by each of the reviewers, and to make a final decision regarding the outcome and the comments to be communicated to the applicant.

Once a final decision has been made, the Ethics Administrator will be asked to send the response to the applicant. At this stage, Ethics Administrators are encouraged to maintain an overview of the decisions being made by supervisors and reviewers, to ensure that decisions (at both the risk assessment and ethical review stages) are being made in line with University and departmental policy, and to identify any training needs. Should an Ethics Administrator become aware of a decision that they have concerns about, they should initially discuss the issue with the Principal Ethics Contact. The supervisor or reviewer concerned may need to be consulted, at which point the decision may be amended. If the Principal Ethics Contact continues to have concerns about the decision made following such a discussion, they should refer the situation to the Head of Department or to the UREC.

Should the department prefer to arrange for an application to be reviewed at a minuted face-to-face meeting rather than online, then the Ethics Administrator should use the 'review by committee' option within the online Ethics Application System and appoint a lead ethics reviewer to coordinate the meeting and record the outcome in the system.

The following sets out the minimum requirements for the ethical review of research (departments can set more stringent requirements if they so wish):

- A minimum of three ethics reviewers is required to undertake a research ethics review of either a staff-led, or a supervised postgraduate-research student application. None of the ethics reviewers may have any conflict of interest with the application (for example, being a co-investigator on the project).
- A minimum of two ethics reviewers is required to undertake an ethics review of a potentially 'high risk' research application from a supervised postgraduate-taught or undergraduate student. At least one of the ethics reviewers must have no conflict of interest with the application. However, one of the ethics reviewers may be the student's supervisor, at the discretion of the academic department concerned.
- Only one ethics reviewer is required to review 'low risk' research applications from supervised postgraduate-taught or undergraduate students. This ethics reviewer may be the student's supervisor. However, academic departments have the discretion to require that more than one ethics reviewer reviews low risk applications from such students, and/or that an ethics reviewer in such a case cannot be the supervisor.
- A minimum of three ethics reviewers must review generic research ethics applications, as defined in Section 3.1.4.2.
- If there is a significant, fundamental difference of opinion between ethics reviewers about the ethics of a proposed piece of research, then a group of at least three alternative ethics reviewers (e.g. an Ethics Review Panel or Research Committee), none of whom should have a conflict of interest with respect to the project in question, must review the application.
- If members of the Ethics Review Panel, or equivalent, cannot reach a consensus then the UREC will undertake an ethics review of the application. If the matter is urgent this may be done through Chair's action, in consultation with other committee members.
- If an application is not approved as a result of an initial ethics review, the applicant may appeal against the initial decision by contacting the department's Ethics Administrator, who should arrange for the Ethics Review Panel or equivalent to review the application. Such an appeal can only be made through the department to which the initial application was submitted. If an applicant wishes to appeal against the decision of an Ethics Review Panel or equivalent, then s/he should contact the Secretary to the UREC, who will arrange for the UREC to review the application. If the matter is urgent, this may be arranged through Chair's action, in consultation with other committee members. The UREC's decision is final.
- Where external ('lay') input to the ethics review process is necessary (due to the requirements of a funding body or any other external body, the cooperation of which is necessary for the research to proceed), ethical scrutiny of research projects will be undertaken by a panel appointed by the University Research Ethics Committee. The panel will be appointed in collaboration with the relevant department, comprising two ethics reviewers from the project's department of origin, one external member from the UREC's pool of external/lay ethics reviewers, and additional members of the UREC as required on a case-by-case basis in order to meet the requirements of the external body. In such cases, the departmental Ethics

Administrator should liaise with the UREC's Minute Secretary to identify appropriate ethics reviewers from the UREC. At least 10 working days should be allowed for external reviewers to submit their review decision and comments, since they undertake this role on a voluntary basis.

Departments have the option of recruiting a wider panel of ethics reviewers over and above the minimum requirements set out above, if the department considers this to be necessary in the context of a particular project. Examples of when this might apply include staff or postgraduate research student applications deemed to present particularly high levels of risk; or where relevant subject matter expertise is not available from within the departmental pool of ethics reviewers.

Where a wider panel of ethics reviewers is deemed to be necessary, the departmental Ethics Administrator should liaise with their Principle Ethics Contact to identify potential reviewers with the appropriate skills and experience and capacity to complete the review. Advice and support can be sought from the relevant Faculty Representative or the Secretary of the UREC, if required.

3.1.7What are the possible outcomes of the ethical review of a project via the University Procedure?
On considering the ethical implications of a project, ethics reviewers can recommend one of the following possible outcomes; the final decision rests with the lead reviewer (or the supervisor in the case of low risk undergraduate/postgraduate-taught student research):

Outcome	***Changes needed by applicant?***	***When can project begin?***
Approval	*No, except for amendments following approval (see section 3.1.9)*	*Once official confirmation of ethical approval has been received via the ethics application system.*
Compulsory changes required	*Yes, to existing application*	*The project cannot go ahead until required changes have been made; the reviewer(s) (normally the lead reviewer) must see the revised version of the application and subsequently approve it.*
Not approved (rejection)	*Re-submission of a new application is usually required*	*The project cannot proceed, for reasons that should be clearly specified by the reviewer(s).*
No decision: this indicates a contentious project, which will need to be reviewed by an Ethics Review Panel,	*Depends on the outcome of the additional ethical review (which will lead to one of the three above outcomes)*	*The project cannot proceed until the additional ethical review process is completed and is dependent on the outcome of that process.*

or equivalent (and if no agreement is reached, by the UREC).		

Ethically approved research must be carried out in compliance with any conditions set by the ethics reviewers, a departmental Ethics Review Panel (or equivalent), or the UREC. If ethics approval is subsequently withdrawn or suspended for any reason, the research must be discontinued.

Where ethics reviewers feel that the applicant has not included sufficient detail for the reviewer to make an informed judgement, they should ask that the applicant clarifies or expands on the information that has been provided before a decision can be made.

Once a final decision has been made, an email notification will be sent to the applicant and a printable letter of approval will be available through the Ethics Application System. The reviewers will be able to access the application as well in order to see the final decision and the comments provided to the applicant. The approval will be valid from the date the final decision is made (or the start date given on the application form, if later) until the end date of the project, as specified on the application form.

3.1.8 How long will it take to obtain ethics approval via the University Procedure?
A relatively straightforward ethics review should ideally take approximately ten working days (the exact timing will depend on the academic department, and circumstances). However, delays can occur if a research ethics application form is not fully completed, if the ethics reviewers request more information/amendments to the application, if an application is judged contentious, or if the applicant appeals against the ethics decision.

Researchers should ensure that they submit ethics applications well in advance of their intended commencement of data collection, to ensure that there is sufficient time for the review process to be completed (including allowing additional time for any compulsory changes to be made and checked). This is particularly important where an external reviewer is required to be involved in the review process (since external reviewers undertake this role on a voluntary basis), and at certain times of year (such as Christmas and summer holiday periods).

Ethics Administrators should make appropriate efforts to ensure that the reviewers they appoint will be available to complete the review within the allotted timeframe (e.g. by checking colleague's calendars). Deadlines set by Ethics Administrators should allow reviewers a reasonable period in which to complete the review; where an external reviewer is required to be appointed, Ethics Administrators should allow at least two weeks for the external reviewer to complete their review.

Appointed ethics reviewers should make every effort to complete reviews within the deadline set by the Ethics Administrator, in order to avoid unnecessary delays to colleagues' and students' research. If a reviewer is unable to perform a review within the defined period (e.g. due to a period away from the University, or sickness), they should alert the Ethics Administrator promptly so that alternative arrangements can be made.

3.1.9 What happens if changes are made to the project after ethics approval has been obtained via the University Procedure?

Unless the changes are very minor corrections of errors in the written information given to participants, the researcher should submit an amendment form by searching for the approved application in the 'My applications' screen in the Ethics Application System and selecting 'submit amendment'. This will open a form enabling the details of the proposed amendment to be outlined, along with any ethical considerations. Any new/amended supporting documents can also be uploaded if required (changes to previously submitted documents should be highlighted e.g. via tracked changes).

Once submitted, the departmental Ethics Administrator will be notified and will appoint an appropriate reviewer, usually the lead reviewer from the original application. If the lead reviewer is no longer available, an appropriate alternative will be identified; this may be another lead reviewer or the Principal Ethics Contact. For students, the amendment will first need to be checked by their supervisor in the same way as a new application.

The reviewer will have the same options available to them as for a full ethics application. If the reviewer feels that the proposed amendments are significant and require further consideration, they should use the 'not approved' option and indicate in the comments that a full new ethics application must be submitted.

A significant amendment refers to a new research approach or method that, had it been planned at the time, would have been outlined in detail on the original research ethics approval application. Examples of this include (but are not limited to):

- engagement with a different group of participants;
- a different method for recruiting participants;
- a different approach to obtaining consent, such as major changes in the information given to participants or in the consent form;
- a different method of data gathering;
- a different venue for data collection; or
- providing incentives or compensation for participation.

This list is indicative, rather than exhaustive. If a reviewer is in any doubt about whether a proposed change is significant, or if they feel additional reviewer opinion(s) should be sought, they should err on the side of caution and require a new ethics application to be submitted.

In some types of research, such as those involving participatory methods, it may be necessary to seek ethics approval for different phases of the same project as it develops over time. In such cases, the researcher should normally submit a new ethics application for each phase, and should provide the reference numbers of any previously approved applications for the same project in response to the question 'Please enter details of any similar applications'. This ensures that the reviewers are aware that the application builds on a previous application, and can seek details of that application where needed. Departments may find it helpful to appoint the same reviewers to applications which are linked in this way, where possible.

3.1.10 *Status of ethics approval granted by the University when the researcher leaves the University*

The University's Ethics Review Procedure is designed to provide ethical review and approval for research projects that are undertaken by University of Sheffield staff and students. Whilst the Procedure may be used to seek approval for projects that are undertaken collaboratively with external researchers/organisations, it does not extend to research that is carried out by individuals or organisations not affiliated to the University (as per the UREC's 'Position statement relating to requests for the University / its departments to ethically review external research projects').

Therefore, if a member of staff leaves the University and wishes to continue a research project for which they have University of Sheffield ethics approval, they should be aware that the approval granted by the University will no longer be valid after the date they leave the University. In addition, if approval needs to be sought for amendments to the project after the research has been moved elsewhere, it is no longer appropriate for the University to consider these amendments. This is because the University no longer has any oversight of the research and no control over how it is carried out: it would be a potential reputational risk to the University to continue to approve such projects.

This means that when a member of staff moves to a new institution, they should seek ethics approval from that institution (in accordance with the procedure that operates there); this process could be carried out in advance of the transfer date to ensure that the research can be continued seamlessly following the move. This will also ensure that there is an appropriate route for seeking approval for any amendments to the project as the research progresses at the new institution.

If the member of staff leaving the University is a member of a research team that is continuing to lead the project at Sheffield, then the University of Sheffield ethics approval will normally continue to apply, even if some minor elements of the project are continued by the departing researcher. However, if the project (or significant elements of it, such as whole work packages) will be led by the departing researcher, ethics approval should be sought from their new institution before any work on the research recommences: the University of Sheffield approval is no longer valid.

In all such cases, the researcher will need to give consideration to the requirements of the relevant data protection legislation. If personal data is to be transferred from one institution to another, this is likely to mean a change in the Data Controller, and research participants should be informed of this and other relevant information relating to the transfer of the research project (for example, new contact details, Privacy Notice, complaints procedures etc.)

4 THE ALTERNATIVE ETHICS REVIEW PROCEDURE

The Alternative Ethics Review Procedure refers to the process that should be undertaken when a researcher wishes to rely upon the ethics approval obtained via an external organisation's ethics review procedure (other than the National Health Service (NHS)'s ethics review process).

Wherever possible, the UREC wishes to avoid a situation whereby a researcher needs to apply for ethics review via more than one ethics review procedure (unless the research is taking place in two or more countries in which case this may be unavoidable). However, it is essential that University of Sheffield research involving human participants, personal data

and/or human tissue is subject to a robust ethics review process before the research commences.

The NHS's Research Ethics Committees operate within a rigorous national framework and are considered to operate a robust ethics review procedure with no further assessment required from the University. Researchers obtaining approval via these Committees are not required to undergo the Alternative Ethics Review Procedure, or to submit details of the ethics approval obtained via these Committees to the University's Ethics Application System. This is because evidence of ethics approval for such research must be verified by the project's research governance sponsor, as part of the requirements of the UK policy framework for health and social care research (see Research Ethics Policy Note no.5 for more details).

However, whenever a researcher wishes to rely on an alternative organisation's ethics review procedure (i.e. not the University Procedure nor an NHS Research Ethics Committee) they must first ensure that the procedure has been assessed as sufficiently robust when compared to the University of Sheffield's Ethics Review Procedure (as per section 4.3 below). Once this has been verified, they must then submit a copy of the ethics approval documentation to the University's Ethics Application System.

It should also be noted that where ethics approval is obtained from an institution outside the UK, if personal identifiable data is to be transferred to the UK as part of the research, the researcher MUST ensure that the requirements of any relevant data protection legislation are met. For further details see Research Ethics Policy Note no. 4.

4.1 Research conducted outside the UK

Research that will take place in another country outside of the UK and will involve human participants and/or collection of personal data or human tissue from that country may require ethics approval via an appropriate ethics review procedure in that country. A review and assessment of the local context, including any legal or ethical requirements pertaining to the research and how any local approval/permissions are obtained, is an essential part of a researcher's preparations for carrying out such a project. Where a local ethics review procedure exists, it may *not* be necessary for the researcher to seek ethics approval via the University of Sheffield's Ethics Review Procedure, providing that the local procedure is judged to be sufficiently robust by the UREC (refer to Section 4.3 for details of the relevant assessment process).

If the ethics review procedure in the other country (or countries) is deemed to be insufficiently robust when compared to the University of Sheffield's Ethics Review Procedure, the University of Sheffield's Procedure applies (although it should be noted that review via the other country's ethics review procedure may still be mandatory). For example, the robustness of local ethics approval may be doubtful if all it involves is obtaining the signature of a local official. A sufficiently robust mechanism is one that helps protect the dignity, rights, safety and well-being of the human participants in the research.

Some departments may prefer to adopt a 'belt-and-braces' approach, in which research ethics review is always undertaken via the University Procedure, regardless of procedures elsewhere. This ensures that departmental, and University, ethical oversight is assured. It is important, therefore, that researchers check the policy of their own department with respect to this issue by contacting their Ethics Administrator or Principal Ethics Contact.

Where a research project involves human participants in more than one country then the expectation is that the appropriate ethics review procedure in each country should apply, where this is required (for example a project taking place both in the UK and in two other countries would require ethics approval via the University Procedure as well as any ethics approval that is required in the other two countries).

Further guidance on undertaking research outside the UK can be found in the Specialist Research Ethics Guidance paper on 'Ethical International and Intercultural Research'.

4.2 Research for which ethics approval will be/has been sought via another institution's ethics review procedure

Where a University of Sheffield researcher is collaborating with a partner institution, it may be agreed that ethics approval should be obtained via the partner institution's ethics review procedure (the normal expectation is for the lead partner to obtain the ethics approval). However, as with research conducted outside the UK, this is subject to the condition that the other institution's ethics review procedure is sufficiently robust (see Section 4.3 for details). If the ethics review procedure in the other institution is deemed to be insufficiently robust when compared to the University of Sheffield's Ethics Review Procedure, the University of Sheffield's Procedure applies (although it should be noted that review via the other institution's ethics review procedure may still be required).

When a researcher joins the University of Sheffield from another institution, they may wish to continue a research project for which ethics approval was obtained from that institution. This is acceptable subject to the condition that (a) the other institution's ethics review procedure is sufficiently robust as set out in Section 4.3; and (b) the other institution considers the approval to continue to be valid. If either of these conditions are NOT met, then the researcher should seek ethics approval for the remaining elements of their research project via the University of Sheffield's Procedure.

If these two conditions are met, clarity should also be sought from the other institution regarding how the consideration of any amendments to the project should be dealt with. In all such cases, the researcher will need to give consideration to the requirements of the relevant data protection legislation. If personal data is to be transferred from one institution to another, this is likely to mean a change in the Data Controller, and research participants should be informed of this and other relevant information relating to the transfer of the research project (for example, new contact details, Privacy Notice, complaints procedures etc.)

4.3 Assessment of an institution's ethics review procedure

A list of institutions with ethics review procedures that have already been assessed as sufficiently robust is provided here.

Where ethics approval will be/has been sought via the ethics review procedure of an institution that already appears on this list, the researcher may proceed to submitting the ethics approval documentation to the online Ethics Application System (see Section 4.4).

Where ethics approval will be/has been sought via the ethics review procedure of an institution that does NOT appear on this list, the researcher must provide the following information to the UREC's Secretary:

- A copy, preferably electronic, of the institution's research ethics application form (or if no application form is used, the list of documents required to be submitted to apply

for ethics approval); this will be compared with the University of Sheffield's research ethics application form, to clarify whether or not the institution's ethics reviewers are reviewing applications against sufficiently similar criteria.
- Information on the ethics review process; in particular, the number of ethics reviewers and details of their employers and roles. If the institution's ethics review procedure has a website in English then the details should be provided.

The UREC's Secretary will review the information provided and confirm whether or not the institution's ethics review procedure is deemed to be sufficiently robust.

If the ethics review procedure of an alternative institution is deemed to be sufficiently robust, the researcher should then proceed to submitting the ethics approval documentation to the online Ethics Application System (see Section 4.4).

4.4 Submitting ethics approval documentation to the Ethics Application System

Once it has been verified that an institution's ethics review procedure is sufficiently robust, as set out in Section 4.3, the researcher must submit the ethics approval documentation to the University's online Ethics Application System. The researcher must create a new ethics application in the System, completing the form as normal until they reach the question asking whether the research is either taking place outside the UK, or is being ethically reviewed by another institution. They should select the appropriate option and then follow the process for submitting copies of:

> (1) the research ethics application form, or research protocol if an application form is not used by the institution (NB. this should name the researcher as a collaborator; otherwise the researcher should include supporting information from the collaborating researcher(s) confirming their involvement in the project); and
> (2) a letter/email from the institution's ethics body confirming its approval of the project.

These documents will be checked by the Ethics Administrator, and the researcher should not proceed with their research until 'approval' by the University (i.e. recognition of alternative ethics approval) is confirmed via the Ethics Application System.

The University of Sheffield
Research Ethics Policy Note no. 1

DEFINING HUMAN RESEARCH PARTICIPANTS, PERSONAL DATA AND HUMAN TISSUE

The Research Ethics Policy applies to research involving human participants, personal data, or human tissue, *unless* an appropriate exemption applies (see section 1.1 of the Research Ethics Approval Procedure).

1 HUMAN PARTICIPANTS

Research involving human participants can be broadly defined as research that:

- directly involves people in research activities through their actual participation as research subjects during which research data will be collected from them: 'actual participation' may involve invasive research processes (e.g. surgery, administration of medications) and/or non-invasive research processes (e.g. interviews, questionnaires, surveys carried out face-to-face, or via telephone, email or the internet, observational research, or participation in an experiment), and may refer to the active or passive involvement of a person;
- indirectly involves people in research activities as research subjects, through their provision of, or access to their, personal data and/or tissue; or
- involves people in research activities while they are acting on behalf of others who are research subjects, during which research data will be collected from them (e.g. as parents or legal guardians of children or mentally incapacitated people, or as supervisors of people in controlled environments, such as prisoners, pupils, asylum seekers, psychiatric patients whether sectioned or not, etc.).

It should be noted that the definition of human participants encompasses individuals whom a researcher may identify as *potential* research participants, as well as those who have explicitly provided their consent to participate in research (and a researchers' obligation to respect individuals' dignity, rights, safety and well-being applies in both cases). It also encompasses cases in which the researcher(s) themselves are a subject of the research.

The nature of participation in research and the degree of commitment and intensity of effort that may be requested from participants, subject to their consent, will vary from one research project to another. Regardless of such variations, however, all research that involves human participation in any of three senses outlined above, whatever the status/position/role of the individual(s) concerned, must be reviewed via one of the routes outlined in the Research Ethics Approval Procedure section of this Policy, *unless* an appropriate exemption applies (see section 1.1 of the Research Ethics Approval Procedure).

A table has been developed using examples to provide further guidance regarding what constitutes human participation in a research project, and therefore whether ethics approval is required. The table can be found at the end of this document.

It should be noted that all research projects will involve or affect people in ways that do not constitute participation in line with the definition above, but which nonetheless require consideration as part of the design and implementation of the project. This may include

members of the public who may be in the vicinity as a project takes place, or University colleagues involved in the processes that take place at various stages of a project. The University's Preventing Harm in Research and Innovation (Safeguarding) policy, and the Good Research & Innovation Practices (GRIP) policy, sets out in more detail a researcher's obligations in relation to these issues.

2 PERSONAL DATA

The University's Research Ethics Policy uses the UK General Data Protection Regulation (GDPR) and Data Protection Act 2018 definition of personal data:

> ''personal data' means any information relating to an identified or identifiable natural (living) person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'

Once an individual's personal data has been robustly anonymised, such that the individual is no longer identifiable, then the data is no longer classed as personal data. However, researchers should consider carefully any situation in which the individual may potentially be re-identified by means that are 'reasonably likely' to be used (e.g. taking into consideration the cost and amount of time required for re-identification and the technology available).

According to data protection legislation, for research undertaken by staff or students of the University of Sheffield, the Data Controller (the individual or organisation which determines the purposes and means of processing personal data) will usually be the University (i.e. not a particular individual or research team). Collaboration with other institutions may result in joint Data Controllers. In practice, in the case of discrete research projects, it is highly unlikely that members of the research team will come into contact with data from other parts of the University that may result in the re-identification of participants whose data has been anonymised. However, researchers should think carefully about this possibility when seeking to anonymise their data; strictly speaking, if there is any possibility that anonymised data could be traced back to the individual that provided it via any other data held by, or likely to come into the possession of, the Data Controller, then the data has in fact only been 'pseudonymised'. This means that it would in fact still be classed as personal data. Two examples of situations in which this problem is more likely to arise include:

- administrative research, in which research staff may have access to central University records that may link data to the participants that provided it;
- types of research in which there are particular identifiers that are widely used outside the research team (e.g. health research involving NHS numbers).

Some personal data also falls under a 'special category of personal data' in the data protection legislation This includes information about:

- racial or ethnic origin;
- political opinions;

- religious or philosophical beliefs;
- trade union membership;
- data concerning health;
- data concerning a person's sex life or sexual orientation;
- genetic data;
- biometric data (where used for identification purposes);

Data that fall into any of the above categories are subject to additional requirements under the GDPR; processing of such data is allowed only in a number of specific circumstances, which are discussed further in the Specialist Research Ethics Guidance Paper, 'Principles of Anonymity, Confidentiality and Data Protection'.

Aside from these regulatory requirements, from an ethical point of view, researchers should consider whether their research involves the collection of other types of information which may be considered sensitive. For example, collecting data about drinking habits may not be seen as sensitive for many people in many situations, but this may be different if collecting data about drinking habits among people who have problems with alcoholism. Further information about topics of research that may be considered sensitive is given in Research Ethics Policy Note no. 6 'Research involving vulnerable people'.

3 HUMAN TISSUE

Human tissue is defined by the *Human Tissue Act 2004* (HTAct) as *relevant material* (the HTA website: www.hta.gov.uk). The relevant materials covered by the HTAct include materials that have come from a human body, whether living or dead, including body parts, organs and human cells. Cell lines are not relevant material under the Act (although primary cell cultures are).

The University's definition of human tissue encompasses the collection and use in research of any blood, tissue or other biological samples taken from a human body, whether or not they are considered to be 'relevant material' according to the HT Act.

For further discussion of the legal, ethical and other issues attendant upon research involving human tissue, see Research Ethics Policy Note no. 11, 'Research Involving Human Tissue', and Specialist Research Ethics Guidance Paper, 'Human tissue research'.

4 EXAMPLES OF HUMAN PARTICIPATION IN A RESEARCH PROJECT

A guidance document providing example scenarios of human participation within research can be found on the next page.

Guidance relating to Research Ethics Policy Note no.1 - Examples of human participation in a research project

The following tables aim to provide further guidance with respect to what constitutes human participation in a research project, and therefore whether ethics approval is required or not. The tables do not seek to cover every possible type of human participation, but to give examples which help to clarify when ethics approval is required. It should be noted that there may be 'grey areas' for which it is still not clear whether ethics approval is needed; these will need to be considered by the UREC on a case by case basis as and when they arise. If you would like the UREC to consider a case, or have an example which could be added to the table below, please contact Lindsay Unwin, Secretary to the UREC (l.v.unwin@sheffield.ac.uk, ext. 21443)

Examples of when ethics approval IS required:

In general terms, ethics approval is required where the project will involve interaction with individual(s)* in order to **collect their opinions and/or personal information as research data, in a systematic way for analysis and/or reporting as research, or as part of a student research assignment**. Research data can be defined as 'the evidence used to inform or support research conclusions'

* 'individual(s)' could refer to members of the public, community groups, stakeholders, clients, experts, academics who are not part of the research team itself, professionals, key informants, consultants, and/or the researcher(s) themselves.

Examples	Why is ethics approval required?
A research project involving asking research questions at an academic conference workshop and collecting responses from the attendees to analyse and publish findings.	Although the attendees will be mainly academics, and may be considered 'experts' on the topic, they still constitute human participants in research as their opinions are being systematically collected for analysis and publication as part of a research project, and hence ethics approval is required.
Holding focus groups and interviews with employees of an organisation to research the training and development opportunities available to them, and publish generalisable findings.	Recruiting individuals from an organisation to obtain their opinions as part of a research project, where opinions will be analysed and research findings will be shared outside the organisation itself, constitutes human participation in research, and hence ethics approval is required.
Systematically collecting or eliciting the opinion of experts on the appropriate parameters for a statistical model, where the aim of the research is to compare and analyse their opinions as research data.	Obtaining the opinions of individuals, whatever their role or status, for the purposes of analysing their opinions as research data, will require ethics approval.
A co-production research project in which the members of a community group will work with the academic	Co-production methodologies may involve external partners in a wide range of ways, including contributing to both the design and the conduct of a project,

researchers to collect and analyse research data from the wider community, including providing their own opinions as research data.	providing their own opinions, contributing to the analysis of data, and/or seeking the opinions of other community members e.g. via interviews. In projects where research data will be collected from the external partners themselves, to inform or support the research conclusions, then ethical approval is required. It should be noted that a phased approach to ethical approval may be appropriate due to the continually evolving nature of this type of research. It should also be noted that even aspects of the project that do not require specific ethics approval may generate complex ethical issues that require careful consideration.
A student teaching assignment in which measurements of brain activity will be taken from students during a taught session, and the data will be stored and then analysed by the students in a workshop a week later.	Although there is no intention for the findings to be published formally as research in this case, the Ethics Policy does specifically cover work of educational value designed to improve understanding of the research process, and as the data will need to be stored for analysis at a later date, there are ethical implications in terms of data protection which need to be considered as part of an ethics application. Hence ethical approval is required.
An experiment in which the researcher places sensors on their own hands in order to collect data on their hand movement.	Although there are no other individuals being recruited to participate in the project, the researcher is still considered to be the 'subject' of the research and the sole participant. As such, ethical approval should be obtained to ensure that due consideration is given to potential ethical risks.
A student undertaking informal interviews with housemates, and recording their conversations, to analyse speech patterns and report findings as part of an essay.	Although undertaken informally with the student's own housemates, this is still collecting data from human participants for the purposes of research. As such, ethical approval should be obtained to ensure that due consideration is given to potential ethical risks.

Examples of when ethics approval is NOT required:

In general terms, ethics approval is NOT required where a project will involve interaction with individuals(s)* **in order for them to contribute only to an activity which does not constitute research (e.g. where they are only contributing to the design of a research project itself, or the design of a specific product, or a news report) with no intention to disseminate the data/findings as academic research.** It should be noted that even where ethics approval is not required, people should be treated in an ethical way (including obtaining informed consent where appropriate), and personal data must be obtained and handled in compliance with the General Data Protection Regulation and Data Protection Act 2018).

Guidance relating to Research Ethics Policy Note no.1 - Examples of human participation in a research project

Examples	Why is ethics approval NOT required?
A staff consultation project to develop a new car part for an external partner organisation, in which discussions are held with the staff of the organisation and an industrial steering group to agree the design parameters, and to discuss progress throughout the project. Outcomes of the discussions are used only by the project team and partner organisation to contribute to the design of the product.	Providing opinions are being obtained from relevant stakeholders solely for the purposes of contributing to the design of a product, and will not be analysed and published as research, or as part of a student's research assignment, this does not constitute human participation in research and therefore no ethics approval is required. NB. If these criteria are NOT met, ethics approval will be required.
A student design project to develop an improved building design, drawing on discussions with building owner and users. Outcomes of the discussions are only used by the student design team (including any supervisors/assessors/examiners for assessment purposes only), and the building owner, to contribute to the design plan.	Providing opinions are being obtained from relevant stakeholders solely for the purposes of contributing to the design of a product, and will not be analysed and published in order to inform or support research conclusions, this does not constitute human participation in research and no ethics approval is required. NB. If these criteria are NOT met, ethics approval will be required.
Focus groups with patients to discuss and advise researchers on how a study should go about recruiting participants from a particular patient group [this may be referred to as Public or Patient Involvement (PPI)].	Providing opinions are being obtained from members of the public or patients solely for the purposes of contributing to the effective *design* of a research project, and will not be analysed and published as research data in order to inform or support the research conclusions, this does not constitute human participation in research and no ethics approval is required. NB. If these criteria are NOT met, ethics approval will be required.
Seeking the opinion of a clinical consultant on best clinical practice in order to inform the interpretation of research data.	Providing opinions are only being obtained from key individuals with relevant experience or expertise, for the purposes of obtaining their views on the research data itself, and/or advising on the implications of the findings, then ethics approval is not required. In this case, the opinions are not being analysed and reported as research data, but are being used to inform the next phase of the research itself, and any individuals consulted in this capacity should be referenced within any publications. NB. If these criteria are NOT met, ethics approval will be required.

Guidance relating to Research Ethics Policy Note no.1 - Examples of human participation in a research project

Interviewing members of the public for purposes of reporting on a piece of breaking news, as part of a student's vocational training as a journalist	Obtaining people's opinions as a news-gathering exercise, for reporting solely as news, does not constitute academic research and hence does not require ethics approval. NB. If these criteria are NOT met, ethics approval will be required.
Contacting an official or representative of an organisation or government body, in order to request information (e.g. statistics) or obtain documents which will inform the research. This process may include clarifying details relating to the information or documents received.	Contacting people in order to seek information or materials which are of research interest does not constitute participation in a research project, and hence does not require ethics approval, providing those people are not being asked to provide personal data or opinions which will be used for analysis as research data. NB. If these criteria are NOT met, ethics approval will be required.
Collecting or eliciting the opinion of experts on the appropriate parameters for a statistical model, where the information provided will not be analysed as research data, but will be used to inform the research method or design.	If opinions are only being obtained from key individuals with relevant experience or expertise, for the purposes of obtaining their views on the research data itself, and/or advising on the implications of the findings, then ethics approval is not required. In this case, the opinions are not being analysed and reported as research data, but are being used to inform the next phase of the research itself, and any individuals consulted in this capacity should be acknowledged (either anonymously, or by name if they have given their consent for this) within any publications.

The University of Sheffield
Research Ethics Policy Note no. 2

PRINCIPLES OF TRANSPARENCY AND CONSENT

1 TRANSPARENCY

Individuals have a right to be fully informed about all the aspects of a research project in which they are considering participating that might reasonably be expected to influence their willingness to participate. The researcher should explain any other aspects of the research about which prospective participants may enquire. Taken together, these aspects of research should normally include:

- the nature and purpose of the project;
- the legal basis for the collection and use of the participants' data (as set out in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general);
- the research methods to be employed by the project;
- full explanation of any technical terms used;
- the conditions under which the project will be conducted;
- who is undertaking and who is sponsoring the project (i.e. the details of the 'Data Controller', the research team, the funder and/or the research governance sponsor if applicable);
- the potential risks and inconveniences that may arise;
- the potential benefits that may result;
- what participation in the research will require in practice and what data will be collected;
- information about the right to withdraw from the research, and how to go about this;
- what will happen to the data and who will have access to it (including any further use of the data beyond the immediate research project, and any intention to transfer data outside of the UK, and the appropriate safeguards that will be adopted);
- how participant confidentiality will be safeguarded;
- how the data will be stored, and when it will be destroyed (or the criteria that will be used to determine when it will be destroyed);
- how to raise safeguarding or other concerns, or to complain, about the research, and to whom (see note below); and
- the consequences of non-participation (such as alternative treatments in the case of some medical research, or alternative educational activities in the case of some educational research).

In connection with the above, it should be noted that the appropriate channels for the registration of complaints within the University, should a participant be unhappy with their treatment and unable to resolve them directly with the researcher and/or research team, is the Head of the relevant department. If a participant has safeguarding concerns, they should be able to report these to a Designated Safeguarding Contact or other named person. Participants should also be informed of their right to contact the Data Protection Officer for the Data Controller organisation, or the Information Commissioner's Office, if they have a complaint about the use of their personal information within the research.

In many contexts, taking into account the language and literacy of potential participants, a

fact-sheet summarising the above is a useful and documented means of providing this information. Further discussion of anonymity, confidentiality and data protection can be found in Research Ethics Policy Note no. 4.

2 OBTAINING INFORMED CONSENT

Prior to a person being able to participate in research activities as a 'research subject/human participant in research', the lead researcher, or their delegate, is responsible for obtaining that person's informed consent to participate wherever it is appropriate to do so, and for documenting this consent. This is an important principle of research ethics.

Consent must be given freely and voluntarily and under no circumstances must direct coercion or indirect pressure be used to obtain a person's consent to participate in research (see section 3 of this Policy Note, dealing with 'Coercion'). Wherever possible, and bearing in mind the nature of the research activity concerned and the research methods to be adopted, an individual's consent should ideally be obtained in writing through their signing of a consent form. This is the 'gold standard' of informed consent.

Where written consent is not possible or would be more onerous for the participant to provide (for example, a participant in another country may feel uncomfortable doing so for political reasons, or when interviews/focus groups are carried out wholly online), electronically recorded consent or documented oral consent, are acceptable alternatives. Electronically recorded consent can be obtained via an electronic (typewritten or scanned) signature on a consent form forwarded form a participants' personal email address, an email from a participants' personal email address in which the participant confirms their agreement to the terms set out in a consent form, or can be sought via an online version of a consent form (e.g. via Google Forms).

Oral consent should either be audio/video recorded or obtained in the presence of at least one witness. Witnessed consent is required for particularly vulnerable participants who have intellectual or cultural difficulties of speech or understanding, but who are deemed capable of giving consent. Witnessed consent should be specified during the ethics approval process and involve an approved form for witness and researcher to sign. In the case of anonymous surveys carried out either in-person or online, where no personal data will be collected from which the participant could be identified, then it is acceptable to simply record the participant's agreement to proceed with the survey via a brief tick-box or similar mechanism (although appropriate information about the project should still be provided in line with section 1 of this Policy Note, to inform a participants' decision).

Records of participant consent should be held securely and separately from the research data. They should normally be retained for an appropriate period after the completion of the project, and as long as the research data are retained in identifiable form (by the researcher or an archive), after which only a template consent form should be retained. Consent forms signed in writing can be digitised, enabling the hard copies to then be destroyed securely by means of shredding.

Giving and obtaining consent is a process, not a one-off event that happens at the beginning of a person's involvement in research, and during their active involvement participants have the right to change their minds and withdraw consent. If a researcher doubts whether a person participating in research still consents to participating they should clarify this with the person in question. However, the right to withdraw cannot, practically, extend to the

withdrawal of already published findings or be invoked in such a way as to compromise aggregate, anonymised data sets. This should be made clear to participants as part of the process of informed consent.

One issue that has created problems with respect to consent concerns people who may be named, or otherwise referred to, in publications arising from the research. In such circumstances, unless it is a matter of a public person acting in their public capacity, the researcher(s) must either (1) anonymise the person, so that they cannot be identified, or (2) ensure that they have obtained the informed consent of the individual concerned.

There are, however, circumstances in which consent may not be possible or necessary, or in which the scope for consent may be constrained by the specific demands or nature of the research. For further details, see the relevant sections contained in this Policy Note, particularly 'Consent in research involving adults who lack mental capacity', 'Consent in research involving children', 'Research involving principled deception', and 'Research in public contexts and with groups', as well as the Policy Note on Research Involving Social Media.

When consent is necessary - which is the case in most research with human participants - researchers should make it clear to potential participants, prior to their participation:

- that they have the right to refuse to participate in the research in question;
- that, at any time during their active participation, they have the right to withdraw from the research, without having to give a reason, regardless of whether payment or other inducements have been offered, and with the assurance that any service or help they are receiving in relation to the research will not be affected in any way; and
- that these rights cannot, however, extend to the withdrawal of already published findings or be invoked in such a way as to compromise anonymised data sets that are being used as specified in the original consent agreement.

In some cases, a prospective participant may, for a range of reasons, be unable to understand the implications of participation. In the case of a pre-competent child, the researcher is responsible for obtaining the informed consent of the parent(s) or legal guardian(s). With respect to adults who cannot understand the implications of participation, however, no-one can in law consent on their behalf, other than in certain clinical situations. Extreme caution should therefore be exercised: when in doubt it is generally better to err on the side of such caution and not proceed. For further discussion, see sections 4 and 5 of this Policy Note.

Where a Research Ethics Committee has specifically instructed a researcher to obtain the informed consent of participants, or where a research funder specifies that informed consent must be obtained from participants as a condition of its award, then fully informed consent must be obtained.

See also the discussion in Research Ethics Policy Note No. 6, 'Research involving vulnerable people'.

3 COERCION

The quality of the consent of participants requires careful consideration, particularly but not exclusively with respect to those who are potentially or actually dependent on the

researcher, the research sponsor, or a research gatekeeper (e.g. as employees, patients, students, and so on). In such cases, willingness to volunteer may be influenced by the expectation of benefits or rewards, or the fear of penalties.

If research is being conducted with detained persons (e.g. prisoners, 'sectioned' psychiatric patients, asylum seekers, elderly people in a residential care home) particular care should be taken over informed consent. Particular attention should be paid in these circumstances to the factors that may affect the person's ability to give informed consent freely and voluntarily.

People volunteering to participate in research may be paid for their inconvenience and time. Financial payments might, for example, cover reimbursement for travel expenses and/or time. However, payments made to individuals to *enable* them to participate in research activities must not be so large as to *induce* them to take risks beyond those that would usually be part of their established life-style. Any risks resulting from participation should be acceptable to participants even in the absence of payment.

Researchers should ensure that if payment is to be offered to participants, it is made clear that by participating in the research, the participant is not entering into any formal contract of employment (which would have legal and tax implications). Further guidance from HR on this issue can be found here: https://www.sheffield.ac.uk/hr/guidance/contracts/volunteers.

Agreements about compensation for damage, injury or loss of income to participants as a result of participating in research activities should be carefully framed, to avoid any possible interpretation as coercion by inducement. If there is any doubt about this, professional legal advice should be sought.

4 CONSENT IN RESEARCH INVOLVING ADULTS WHO LACK MENTAL CAPACITY

Research with adults who are considered to lack mental capacity is very complex, legally and ethically. The relevant legal framework can be found in (a) the Mental Capacity Act (2005) and (b) Directive 2001/20/EC of the European Parliament and of the Council (*Good clinical practice in the conduct of clinical trials on medicinal products for human use*), implemented in England in the *Medicines for Human Use (Clinical Trials) Regulations 2004/1 03*.

Legally, consent to research can be given on behalf of non-competent adults, but only with respect to clinical research that is specifically concerned with their medical condition, and only under tight regulation.

This does not mean that non-clinical research with adults with learning disabilities or mental health problems, for example, is impossible. It does mean that gaining consent in such cases will be complex and require imaginative and inclusive approaches to the provision and explanation of information about research participation. An inability to obtain defensible informed consent should, therefore, not simply be assumed; the need for effort and innovation, based on inclusion and respect, in providing information on which to base consent, should. There are no easy or formulaic approaches to the negotiation of informed consent with adults who are deemed to lack mental capacity.

Some of these complex and sensitive issues are discussed in further detail in the Specialist Research Ethics Guidance Papers entitled 'Research involving adult participants who lack the capacity to consent' and 'Doing research with people with learning disabilities'.

5 CONSENT IN RESEARCH INVOLVING CHILDREN

If infants, children and/or young people under the age of eighteen are involved in a research project, where appropriate and feasible the informed consent of one of their parents or their legal guardian should be obtained. However, in some circumstances obtaining the informed consent of a parent may be inappropriate (e.g. research with children who have been abused by a parent) or infeasible (e.g. research involving homeless children).

When possible, a researcher undertaking research with children and/or young people under the age of eighteen should *also* obtain the child's or young person's free and voluntary consent to participate. However, the ability of a child to give free and voluntary consent depends on that child's competence, which varies with age, experience and confidence. The type of research that s/he is being invited to participate in, and the skill with which the researcher talks with that child and helps them to make free and voluntary informed decisions, are also significant factors. Even if a child is deemed insufficiently competent to give fully informed consent, their assent (e.g.. willingness or agreement) to participate should still be sought.

So, as a general principle, where a child or young person under the age of eighteen participates in research, researchers should, *when this is possible*, obtain the informed consent of both a parent or legal guardian *and* the consent or assent of the child (regardless of whether or not the research is invasive or involves sensitive topics). This principle may be set aside where a parent or legal guardian is not available *and* it can be demonstrated that the research is not against the best interests of the child or young person concerned. Children aged 16 and older are assumed to be capable of giving consent for their participation in clinical trials of Investigational Medicinal Products, without the need for parental consent.

Within the NHS, the Confidentiality Advisory Group (CAG)) has the authority to override the need for consent where it is infeasible, under Section 251 of the NHS Act 2006 (e.g. CAG has ruled that it is not necessary to have patient consent to use their data in a cancer registry; similar assurances have been made for epidemiological research concerned with CJD).

In the case of research in educational settings, any special school policies or procedures should be followed.

For further discussion, see the Specialist Research Ethics Guidance Papers entitled 'Principles of anonymity, confidentiality and data protection' and 'Ethical considerations in research with children and young people'.

6 RESEARCH INVOLVING PRINCIPLED DECEPTION

In certain research disciplines (such as psychology and anthropology) it may sometimes be necessary to withhold information about the true objectives of the research from the people participating in it in order to ensure the viability and validity of the research. In research of this kind it is inappropriate to obtain informed consent from the participants. Wherever possible such research should be avoided and ethics reviewers should pay particular attention to this issue. However, when such research is judged to be necessary, researchers

should exercise particular caution. In these circumstances the lead researcher has two, equally important, special responsibilities under this Policy:

- to demonstrate unequivocally in the research ethics application that alternative procedures to avoid withholding information or deliberate deception are not available, or, if available, are not feasible for the particular research in question; and
- to explain in detail why withholding information, or an element of concealment or deception, is necessary for the viability and validity of the research.

Another type of research that falls under the heading of 'principled deception' is covert research, in which the very fact that research of any kind is being undertaken is deliberately concealed. Examples in the past have included research into criminal activity, ultra right-wing political organisations, and secretive religions: these are all settings in which informed access is (a) unlikely and (b) likely to alter the behaviour of those present. This is research that has much in common with investigative journalism, and it can be very controversial, not least when the 'participants' discover that they have been researched. Typically, it is justified by a 'public interest' defence. Research of this kind should only be considered in the most unusual circumstances. In such circumstances the lead researcher has four, equally weighty, special responsibilities under this Policy:

- to provide a convincing case for researching the topic or organisation in question;
- to demonstrate unequivocally that the research in question cannot be done using any other, more transparent 'above board', approaches;
- to explain in detail what steps will be taken to protect, and to monitor the safety and well-being of, the researcher(s); and
- to explain in detail what steps will be taken to protect, and to monitor the welfare, dignity and rights of, the participant(s).

In some cases of research involving principled deception, retrospective consent may help to ensure that the research is, and is seen to be, properly ethically managed. In these cases, participants may be informed of the nature of the deception involved via a de-brief at an appropriate point, and their consent to publication or other dissemination can then be sought. In such cases, researchers should be prepared for refusals and should notify funders, where relevant, of this possibility.

7 CONSENT IN PARTICIPANT AND NON-PARTICIPANT OBSERVATION

There is a 'grey area' with respect to consent in ethnographic research, particularly participant observation in which the researcher sets out to become a part of the social setting that is the context or focus of the research. This is an established research approach, but it entails risks of misunderstanding that underline the need to regard consent as an ongoing process of negotiation and discussion.

In particular, among others, the following scenarios are possible:

- local participants may over time 'forget' that the researcher is actually only in the setting in question as a researcher, to collect data;
- the researcher and participants may forge personal relationships of friendship in which the norms of confidence and openness will differ from those that apply in a research

relationship; and
- there may be situations in which the researcher is unsure of their role, particularly with respect to when they are 'off duty' as a researcher.

The boundaries between the personal and the professional may become blurred. In some sense, situations such as these are a mark of successful participant observation, but they may result in inappropriate or risky personal disclosures. In such cases the researcher has an imperative duty of care to participants: to exercise confidentiality, as much vigilance as possible, judgment, and restraint in the use of data. When in doubt, it may be best to destroy any field notes about which there is a question, or at least not use the material. It may be even better to exercise caution with respect to what is recorded in the first place.

See also the discussion in Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in participatory research / participatory action research'.

9 RESEARCH IN PUBLIC CONTEXTS AND GROUPS

In certain types of research obtaining consent from every individual present is neither practical nor feasible (e.g. observing behaviour in public places, attending large meetings, attending a music concert or play). Research of this kind stretches the definition of what it actually means to be a human participant in research. In research of this kind researchers should ensure the following:

- that such research is only carried out in public contexts, defined as settings which are open to public access;
- that, if relevant, approval is sought from the relevant authorities;
- that, if relevant, appropriate stakeholders are informed that the research is taking place;
- that specific individuals should not be identified, explicitly or by implication, in any reporting of the research, other than public figures acting in their public capacity (as in reporting a speech by a named individual, for example); and
- that attention is paid to local cultural values and to the possibility of being perceived as intruding upon, or invading the privacy of, people who, despite being in an open public space, may feel they are unobserved.

If individuals may be photographed or filmed as part of a research project, then the potential for people to be identifiable in the resulting materials should be considered carefully. Data protection legislation must be complied with in any case where identifiable material will be obtained. For further guidance (e.g. concerning how to provide appropriate information to people who may be filmed in a public space) is provided in the 'surveillance' guidance developed by the Information Commissioner's Office: https://ico.org.uk/media/1542/cctv-code-of-practice.pdf

The privacy and psychological well-being of people participating in observational research or in research activities in which the researcher may actually be acting as a fellow participant, for example as part of a wider group, must be respected. In such group-based, participatory research activities every effort should be made to ensure that the group leader(s), or others in positions of responsibility, as well as other individuals of a group, understand they are being observed for research purposes. In such activities researchers should at least obtain the consent of the group leader(s) or the consent of others in positions of responsibility to

undertake the research.

It is recognised that in certain types of observational research or organisational settings it may be more difficult to explain to people participating their right to withdraw. However, in such types of research, researchers are expected to consider whether it is practicable, and to take this approach wherever possible.

For further discussion, see Research Ethics Policy Note no. 14 'Research Involving Social Media Data' and the Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in participatory research / participatory action research'.

10 AUTO-ETHNOGRAPHIC RESEARCH

In auto-ethnography, the researcher uses her/his own life experience as a primary source of data. Since no life is lived in isolation, information about other people can never be completely excluded from auto-ethnography. These other people are, therefore, indirect participants, raising questions about their opportunity to exercise informed consent with respect to the nature of their representation in auto-ethnographic material. In principle, informed consent should always be sought from anyone who may be recognisable in an auto-ethnographic account. For further discussion of auto-ethnography, see the Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in autoethnographic research'.

The University of Sheffield
Research Ethics Policy Note no. 3

PARTICIPANT AND RESEARCHER SAFETY AND WELL-BEING

Researchers have a responsibility to protect participants from any harm arising from research. As a general rule, people participating in research should not be exposed to risks that are greater than, or additional to, those that they encounter as part of their normal lifestyles.

These responsibilities are outlined in the University's Preventing Harm in Research and Innovation (Safeguarding) Policy, which details how researchers should ensure that they are aware of the potential risks to their own safety and well-being, as well as that of participants, and wider communities which may be involved in or affected by the research activities. Researchers should consider carefully how these risks can be managed and mitigated (e.g. by undergoing a risk assessment process, implementing a lone working policy, etc. – further guidance may be found on the University's Health and Safety webpages, and departments may have their own policies and procedures in place). Relevant considerations should also be set out fully as part of the ethics application.

Potential risks to participants' safety and well-being should be discussed as part of the informed consent process. This may include asking participants about any factors, such as pre-existing medical conditions, that might create risks to them if they were to participate in a given research project. Participants must be advised of any special action that they should take to avoid risk. Researchers also need to be prepared to respond appropriately to participants should issues arise (e.g. through offering advice, or referral to appropriate agencies/services).

Before participating, people should be informed of how to contact the lead researcher or the Head of Department if they have a complaint about the research, who will be able to escalate their concern within a reasonable time period. Furthermore, if participants have concerns regarding potential exploitation, abuse or harm resulting from the research, then they should be informed of the available routes to report their concern. This should comprise of at least two options, including at least one Designated Research Contact from within the research team, and an appropriate member of staff who is independent of the research team.

If a researcher obtains evidence of physical or psychological problem during the research, then the researcher has a responsibility to inform the participant if they believe that by not doing so the participant's future well-being may be compromised or diminished. If the researcher is not qualified to offer assistance, then an appropriate source of professional advice should be recommended to the participant. For some types of research the giving of advice will be appropriate, intrinsic to the research, and will have been agreed prior to the person's participation as part of the consent process.

In the case of clinical trials, research should only take place where the foreseeable potential risks and inconveniences to the prospective participants are deemed likely to be outweighed by the potential benefits for them and others who have not taken part in the research. In certain cases a participant may explicitly support a research project and support invasive treatment that may be very harmful if, due to the particular circumstances (for example, if

they are terminally ill, they may feel that it is worth taking a significant, potentially life-threatening risk). This example represents the point at which participants may feel that they have a right to participate as well as a right to withdraw, a right to be harmed, in exceptional circumstances, as well a right to be protected from harm.

In the case of non-invasive research methods such as interviews and questionnaires, the content and line of questioning may be sensitive, may raise confidential personal issues, and may intrude, or be perceived to intrude, upon a participant's comfort and privacy (e.g., a seemingly simple question asking for a person's gender may cause distress as not everyone will identify themselves as 'male' or 'female'; such information should only be sought if relevant to the research question, and an appropriate range of options should be included – further guidance on this issue can be found on the Equality and Human Rights Commission's website: https://www.equalityhumanrights.com/en/publication-download/research-report-75-monitoring-equality-developing-gender-identity-question). The initial judgement about whether or not questions are sensitive and likely to cause harm or discomfort rests with the lead researcher. For advice in such cases, the lead researcher should initially consult their departmental Principal Ethics Contact.

Finally, it should be noted that it may not be possible for researchers to identify every eventuality that may arise in the course of a research project, and that this Policy is not designed to cover all possible situations. Unexpected incidents affecting the safety or well-being of those involved, and/or presenting a potential reputational risk to the University, may arise even in a project that has been well-considered and thoroughly ethically reviewed. Should such an incident arise, the researcher should take appropriate steps to manage the immediate situation in line with the University's Health and Safety procedures, and/or where relevant, the Preventing Harm in Research and Innovation (Safeguarding) Policy. At the earliest opportunity they should make their supervisor or line manager aware of the situation. Where there are potential implications relating to research ethics (e.g. if the terms of ethics approval have been breached), the UREC's Secretary should be contacted for advice.

The University of Sheffield
Research Ethics Policy Note no. 4

PRINCIPLES OF ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

For a detailed discussion of the law on which University policy in this respect rests, see the Specialist Research Ethics Guidance Paper, 'Principles of anonymity, confidentiality and data protection', of which the following is no more than a brief summary.

A researcher who processes (collects, stores, uses, discloses or destroys) identifiable personal information - as defined as in the next paragraph - about living individuals, must comply with the requirements of the relevant data protection legislation, and the Common Law Duty of Confidentiality. A researcher who processes identifiable personal information about deceased individuals, must still consider the requirements of the Common Law Duty of Confidentiality. The processing of robustly anonymised personal information, whether relating to the living or the deceased, falls outside the scope of these legal requirements.

Data protection legislation applies to 'personal data'. This is defined in the UK General Data Protection Regulation (GDPR) as 'any information relating to an identified or identifiable natural (living) person ('data subject'). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number[1], location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person'.

According to data protection legislation, any processing of personal data must have a defined 'Data Controller' in place (the organisation which determines the purposes and means of processing personal data). For research undertaken by staff or students of the University of Sheffield, the Data Controller will usually be the University of Sheffield (i.e. not a particular individual or research team). Collaboration with other institutions may result in joint Data Controllers; in such cases, a formal agreement should be put in place to ensure that responsibilities and expectations with respect to data protection and security are clearly set out.

In practice, in the case of discrete research projects, it is highly unlikely that members of the research team will come into contact with data from other parts of the University that may result in the re-identification of participants whose data has been anonymised. However, researchers should think carefully about this possibility when seeking to anonymise data; strictly speaking, if there is any possibility that data could be traced back to the individual who provided it via any other data held by, or likely to come into the possession of, the Data Controller, then the data has only been 'pseudonymised', which means that it would still be classed as personal data. Two examples of situations in which this problem might arise include:

- administrative research, in which research staff may have access to central University records that may link data to the participants that provided it;
- types of research in which there are particular identifiers that are widely used outside the research team (e.g. health research involving NHS numbers).

[1] An 'identification number' does not refer to an anonymous code used to, for example, match participants' responses across different time points.

The use of identifiable personal information in research should be reduced so far as possible consistent with achievement of the research aims. Thus researchers should think carefully about (a) whether it is necessary to use identifiable personal information, (b) the earliest stage at which de-identification might be possible without compromising the integrity of the research and (c) whether full, robust anonymisation could be achieved. All uses of personal information should be defensible as accurate, relevant and not excessive.

If it is necessary to use identifiable personal information, then an appropriate legal basis for the processing of this data must be identified. The University's view is that for research undertaken at the University, this will normally be that 'processing is necessary for the performance of a task carried out in the public interest'. This is set out in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general. Providing this legal basis is applied, it may be possible to use personal data without consent - e.g., when the material is already in the public domain. However, from an ethical perspective, consent is still the normal expectation, unless it can be shown to be inappropriate for some reason. Further information can be found in Research Ethics Policy Note no. 2 'Principles of Consent'.

When gathering identifiable personal information researchers should ensure that its processing is defensible as 'fair, lawful and undertaken in a transparent manner'. This requires that the participant be provided with appropriate information about how the data will be used and any risks that might be involved. However, from an ethical perspective, research participants should be provided with information of this nature even when no personal identifiable information is being obtained.

Personal information must be kept secure at all times. This applies to both physical data (such as signed hard copy consent forms) and digital data. For digital data, researchers should only use the IT products provided by IT Services [Link to further guidance to be added].

If a researcher intends to use an alternative third party system (i.e. one not supplied by the University) to collect, manage or store personal data, then due diligence must be undertaken on the supplier and appropriate contracts must be in place. A careful and thorough assessment of the security of those systems must be undertaken. In such instances, researchers must contact the IT Services Business Relationship Manager for their faculty for advice *(Note: the assessment process may take some time depending on current demand).*

If a researcher intends to develop their own system(s) (e.g. a bespoke software programme) or maintain their own equipment (e.g. a personal computer/external storage) for the purposes of the research, a careful and thorough assessment of the security of those systems must be undertaken. It is recommended that researchers review the University's IT Code of Connection and then contact the Information Security Team for advice if any further support is required.

Personal information should not be retained for longer than necessary. However, it is recognised that research may require the retention of data for long periods and that this may be justified, for example due to funder requirements. Participants should be given full information about how their data will be used, how it will be stored and for how long (if the latter is not possible, then participants should be informed of the criteria that will be used to determine retention periods.)

Personal data that are processed for research purposes may be exempt from a GDPR subject-access request. In general, the disclosure of identifiable information, including information that

may be identifiable to others, should be avoided wherever possible. If it is necessary to disclose personally identifiable information, or information that may be potentially identifiable, then this should usually only be done with the consent of the individuals involved.

The Common Law Duty of Confidentiality applies to research, as to all other activities. Individuals have a reasonable expectation of privacy with respect to confidential information that refers to them. If confidential information about an individual is used for a purpose which an ordinary person would not reasonably expect, this would constitute a breach of confidence.

All researchers wishing to submit a University ethics application must successfully complete three online Information Security courses provided by the University (Protecting Information; Protecting Personal Data; and Protecting Research Data) before their application can be completed. This aims to ensure that researchers' have an awareness and understanding of key data protection and security issues, in order to help ensure that data collected for research are managed in line with data protection legislation and to mitigate risks to participants, researchers and the University.

It is recommended that researchers (in particular, staff and postgraduate research students) develop a data management plan (DMP), which describes the data that will be collected during a research project and how it will be managed, both during and after the project. Further guidance, including links to resources provided by the Library, can be found in the UREC's guidance document 'Should Data Management Plans be submitted as part of an ethics application?'.

For further discussion, including information regarding the additional requirements applying to the collection and use of 'Special Categories' of personal data, see the separate Specialist Research Ethics Guidance Paper entitled: 'Principles of anonymity, confidentiality and data protection'.

The University of Sheffield
Research Ethics Policy Note no. 5

ETHICS REVIEW OF HEALTH AND SOCIAL CARE RESEARCH IN THE UK

The University of Sheffield's Research Ethics Policy is intended to complement the long-established National Health Service (NHS) ethics review system (overseen by the Health Research Authority (HRA) and incorporated into the HRA Approval process) The University's Ethics Review Procedure does not duplicate the functions, or overlap with the remit, of the NHS ethics review system.

It should be noted that, in addition to the requirement for ethical review, health and social care research in the UK is subject to additional research governance requirements, which includes the requirement for a research governance sponsor to be appointed. For more details refer to the following webpage: https://www.sheffield.ac.uk/rs/ethicsandintegrity/governance.

It should be noted that in the UK, for clinical trials of Investigational Medicinal Products (IMP-trials) or Medical Devices, and for research involving the use of human tissue or human embryonic stem cell lines, there are specific legal and regulatory requirements which must be considered alongside the requirements for ethical review. Further information relating to the requirements for IMP-trials and Medical Device trials can be found in sections 1.2 and 2 of this Policy Note, and the MHRA's website (https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency). Further information relating to the use of human tissue in research is provided in section 2 of this Policy Note and in Research Ethics Policy Note no. 11.

In addition, there is a legal requirement for social care research involving adults in England and Wales who are deemed to be lacking in capacity to be reviewed by a recognised Appropriate Body under the Mental Capacity Act 2005. Appropriate Bodies are all NHS Research Ethics Committees, including the designated Social Care Research Ethics Committee; for full details see section 3 of this Policy Note and the Specialist Research Ethics Guidance Paper entitled 'Research involving adult participants who lack the capacity to consent'.

1 DEFINITIONS

1.1 Research

The University's Research Ethics Policy defines research as 'a process of investigation leading to new insights, effectively shared'.

The HRA defines research as 'the attempt to derive generalisable or transferable new knowledge to answer questions with scientifically sound methods'; a decision tool is provided which can be used to establish whether a study is defined as research by the HRA:

http://www.hra-decisiontools.org.uk/research/

The University's definition of research is broader than that of the HRA. This means that some studies which are not considered research by the HRA, and which therefore do not require ethical review by an NHS Research Ethics Committee, will still require ethical review via the University's Ethics Review Procedure if they involve human participants, personal data or human tissue. This includes, for example, studies classed as service evaluation or audit by the

HRA, but which are undertaken by a student as the research element of a University degree award, or are undertaken with the intention to disseminate the findings beyond the service being evaluated/audited).

The difference between the University and NHS definition of research can introduce additional complexities which require careful consideration. For example, a project classed as a service evaluation or audit may not require patient consent from the NHS perspective, but the normal expectation of the University would be for patient consent to be obtained. Where such issues arise, further advice should be sought from the UREC so an appropriate approach can be agreed. The normal expectation is that the clinical care team should be asked to extract the required details and provide an anonymised data set for the researcher to analyse for the research, so the researcher does not have to access any identifiable patient data).

1.2 Health care research

The '*UK policy framework for health and social care research* (2017) defines health care research as:

> Health and social care research that is within the responsibility of the HRA or the Devolved Administrations' Health Departments. This includes: research concerned with the protection and promotion of public health; research undertaken in or by a UK Health Department, its non-Departmental public bodies and the NHS, and social care providers; and clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken within the health and social care systems that might have an impact on the quality of those services.

In practice, the University considers research that requires review by an NHS Research Ethics Committee and/or which requires HRA Approval to be health care research (see section 2 of this Policy Note for more details).

Clinical trials of investigational medicinal products (IMP-trials), which are one type of health care research, are defined by the International Conference on Harmonisation Guideline on Good Clinical Practice (ICH-GCP) as:

> Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s) and/or to identify any adverse reactions to an investigational product(s) and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms clinical trial and clinical study are synonymous.

Research involving human tissue is one type of health care research. The Human Tissue Act (2004) defines human tissue as 'relevant material that has come from a human body and consists of, or includes, human cells'.

1.3 Social care research

Social care research refers to research that is undertaken in or with bodies (either independent or statutory) that provide personal social services.

Local social care providers will have their own research governance requirements, and researchers will need to refer to the relevant provider in order to determine which types of project will be affected. For example, the definition of social care research applied by Sheffield City Council is '"the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods"; the methods may include questionnaires, interviews, surveys, observation etc, and may involve our staff, service users and carers. This definition includes studies that aim to generate hypotheses as well as studies that aim to test them.'

It should be noted that not all social care research requires access to human participants via statutory social care services.

2 ETHICS REVIEW PROCEDURE FOR HEALTH CARE RESEARCH

Most health care research will require review by an NHS Research Ethics Committee (NHS REC). Review by an NHS REC forms part of the HRA Approval process. The remit of NHS RECs is defined by the Department of Health's policy document *Governance arrangements for research ethics committees.*

In general, review by an NHS REC will be required for research that involves participants identified in the context of, or in connection with, their past or present use of NHS/social care services or the health/social care services of the UK Devolved Administrations. There are also specific types of health care research that will require review by an NHS REC (e.g. a clinical trial of an Investigational Medicinal Product and research involving human tissue). Research involving only the premises and/or staff of the NHS or other health services does not require review by an NHS REC (but may still require HRA approval). Researchers should refer to the HRA's ethics decision tool for full details:

http://www.hra-decisiontools.org.uk/ethics/

The University requires all research involving human participants, their data or their tissue to be ethically reviewed. This means that research that falls outside the remit of NHS RECs, but which involves human participants, their personal data or tissue must be reviewed via either the University's Ethics Approval Procedure or an Alternative Ethics Review Procedure (for further information about the latter, see section 4 of the University's Research Ethics Approval Procedure). It should be noted that this may include studies that the NHS considers to be service evaluation or audit, and those which involve NHS staff or premises.

3 ETHICS REVIEW PROCEDURE FOR SOCIAL CARE RESEARCH

A small number of NHS Research Ethics Committees are 'flagged' to review social care research. Particular categories of social care projects, including social care studies funded by the Department of Health, and social care research that involves people lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005, will require ethical review by one of these social care-flagged NHS RECs. Full details can be found on the HRA's website:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/social-care-research/

If social care research does not require review by an NHS REC, but involves human

participants, personal data or human tissue, it must be reviewed using the University Ethics Review Procedure, on the proviso that the requirements of the ESRC *Framework for Research Ethics* are met. This means that the ethical scrutiny of social care research projects of this kind will be undertaken by a sub-committee of the UREC, comprising two ethics reviewers from the project's department of origin, one lay member from the UREC, and additional members of the UREC as required on a case-by-case basis in order to meet the requirements of the external body.

The researcher should indicate that the project is 'social care research requiring review via the University Research Ethics Procedure' by ticking the relevant box on their ethics application form. This will ensure that their departmental Ethics Administrator is notified of this requirement and can then liaise with the UREC Minute Secretary to arrange appropriate ethical review.

3.1 Mental incapacity

The University's Ethics Review Procedure cannot review research that involves adults in England or Wales who are defined as lacking mental capacity. Only Research Ethics Committees that are recognised as *Appropriate Bodies* for this purpose can do so under the Mental Capacity Act (MCA) 2005 (these are also sometimes known as 'flagged committees' for the purposes of such reviews). All NHS RECs established in England and Wales are recognised for this purpose. The MCA generally applies only to people aged 16 and over, but there are exceptions.

The MCA Act 2005 does not apply to Scotland or Northern Ireland, both of which have their own laws governing the involvement of people lacking mental capacity in research.

For further information, see the Specialist Research Ethics Guidance Paper dealing with 'Research involving adult participants who lack the capacity to consent' and the HRA's webpages: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/.

The University of Sheffield
Research Ethics Policy Note no. 6

RESEARCH INVOLVING VULNERABLE PEOPLE

From the initial research design stage onwards research involving human participants must prioritise how the research process and results are likely to impact upon those who will be directly involved as participants as well as those for whom the research has relevance. This is part of the duty of care owed by the University's staff and students to all people who may be involved or affected by the University's research activities, and is detailed within the Preventing Harm in Research and Innovation (Safeguarding) Policy.

The responsibility for conducting research rigorously, respectfully and responsibly, from start to finish, is magnified when undertaking research with people who are considered to be vulnerable. However, the term vulnerability is open to many interpretations. Certain people or groups of people are potentially more vulnerable than others.

The degree of vulnerability of an individual will depend on a range of factors, some of which can be anticipated and some not. Therefore researchers should take particular care to:

- anticipate and prepare for foreseeable ethical challenges, in order to protect the participant(s), themselves and others who may be present during the research activities;
- adhere to recognised research ethical principles and any associated legislative requirements (e.g. consent, confidentiality, etc.); and
- remain pragmatic and flexible in ensuring these principles are applied rigorously.

The type of participants, the research methods employed, and the sensitivity of the subject being researched will all play a part in determining the degree to which participants are vulnerable.

1 THE CONCEPT OF VULNERABILITY

All human participants in research may be potentially vulnerable. Some participants may, however, be particularly vulnerable (as described below). Some people may not perceive themselves to be particularly vulnerable. However, there are certain groups that must be considered as vulnerable and appropriate steps taken to account for this.

There are three basic kinds of vulnerability:

- vulnerability to physical harm;
- vulnerability to damage to social standing or reputation; and
- vulnerability to psychological and emotional distress.

These types of vulnerability may occur in combination. People may be vulnerable in different ways and to different degrees at different points in their lives, due to the circumstances in which they find themselves at a particular time. However certain vulnerable individuals may be at more risk of harm when taking part. Accordingly, researchers cannot take it for granted that standard procedures (e.g. for seeking consent) will be appropriate and for some

vulnerable groups it is essential that their specific requirements are taken into account and addressed when designing and undertaking research (for example when developing appropriate information content).

Among the categories of people who are perceived to be likely to be particularly vulnerable in a research context are:

(a) People whose competence to exercise informed consent is in doubt, such as:

- infants and children under 18 years of age;
- people who lack mental capacity, may be at risk of losing capacity or have fluctuating capacity for example people with learning disabilities, people with dementia or conditions that give rise to cognitive impairments such as stroke;
- people who suffer from psychiatric or personality disorders, including those conditions in which capacity to consent may fluctuate; and
- people who may have only a basic or elementary knowledge of the language in which the research is being conducted.

(b) People who may socially not be in a position to exercise unfettered informed consent, such as:

- people who depend on the protection of, or are controlled and influenced by, research gatekeepers (e.g. school pupils, children and young people in care, members of the armed forces, young offenders, prisoners, asylum seekers, organisational employees);
- family members of the researcher(s); and
- in general, people who appear to feel they have no real choice on whether or not to participate.

(c) People whose circumstances may unduly influence decisions to consent, such as:

- people with disabilities;
- people who are frail or in poor health;
- elderly people;
- people who are in care;
- relatives and friends of participants considered to be vulnerable;
- people who feel that participation will result in access to better treatment and/or support for them or others;
- people who anticipate any other perceived benefits of participation; and
- people who, by participating in research, can obtain perceived and/or actual benefits to which they otherwise would not have access e.g possibility of a new medication being available, payment for participation.

The above is not intended to be a comprehensive list, it is merely indicative of the range of situations in which questions about the vulnerability of research participants must be addressed.

Vulnerability should not simply be seen as a property or characteristic of individuals or

categories of people. The research process may increase the potential vulnerability of participants, of a participant's relatives, friends and others who have a relationship to the participant, and of the researchers themselves. Similarly, research into sensitive topics may also increase a participant's vulnerability to harm or distress.

What is perceived as vulnerability in one research discipline may not be perceived as vulnerability in another; some disciplines and research areas also have specific legal, regulatory and/or governance requirements relating to vulnerable participants which must be met (e.g. for health and social care research). The type of research method and the subject matter of the research also affect the nature and degree of participant vulnerability.

Different research methods present different risks to participants; these may be risks that increase the vulnerability of the participants. Researchers should put in place measures to manage and to mitigate foreseeable risks. This may include, for example, research which involves in depth qualitative enquiry and/or requires the participant to use or recall experiences or incidents that may cause distress. The sensitivity of the subject matter being researched is also significant in this respect. For example, a research project focusing on any of the following subjects may increase the vulnerability of participants (although not an exhaustive list):

- 'race' or ethnicity;
- political opinion;
- trade union membership;
- religious, spiritual or other beliefs;
- physical or mental health conditions;
- sex life, sexuality and/or gender identity;
- identity of an individual resulting from processing of genetic or biometric data;
- abuse (child, adult);
- nudity and the body;
- criminal or illegal activities;
- political asylum;
- conflict situations;
- personal violence;
- terrorism or violent extremism; and
- personal finances.

Conducting research ethically is not, however, a matter of avoiding potentially high-risk research. It is, rather, about preparing for and managing risks; it is a matter of being risk aware, not risk averse.

2 SOME IMPLICATIONS FOR RESEARCH

All research should be conducted as skilfully and as carefully as possible. Researchers must ensure that they themselves, and any collaborators or members of a research team or students under their supervision, comply with legal requirements in relation to working with infants or children or vulnerable adults.

The principles that govern all research involving human participants should be adhered to with even greater diligence when research involves vulnerable participants; this includes the requirements of the Preventing Harm in Research and Innovation (Safeguarding) Policy. When

designing the research, including the informed consent process, and when conducting, communicating and publishing research the researcher should consider the perspectives of actual or prospective participant(s). Depending on the nature of the research, the researcher should also give consideration to how to manage the relationships with participants post-research, for example by offering to send them a summary of the results.

Researchers who collect information about the characteristics and behaviours of individuals and groups should where possible avoid using classifications or designations that give rise to unreasonable generalisations, resulting in the stigmatisation of, or prejudice towards, the group(s) in question.

3 THE IMPORTANCE OF CONTEXT

It is important to be aware that prospective participants may be vulnerable, but not to assume that they are particularly vulnerable. Each person is unique with a distinct personality. Therefore, it is worth reflecting that within groups defined as vulnerable there may be significant variation in degrees of vulnerability.

Context is an important factor in influencing vulnerability, such as, for example, the location in which the research is undertaken, the social-economic background of the participants, or the culture and living conditions of the participants. The combination of the research context and the particular research design has the potential to increase the vulnerability of participants.

4 GENERIC PRINCIPLES FOR CONDUCTING RESEARCH INVOLVING VULNERABLE PEOPLE

The following are useful generic principles that should be taken into account when doing research that involves vulnerable people:

- Be reflective at all times about one's research actions and research decisions.
- Be aware that the particular characteristics of a research project can affect the nature and degree of participant vulnerability.
- In designing the research seek to minimise the potential risks to prospective participants.
- Be aware of the possible need to support participants on completion of the research, and prepare for this accordingly (not least with respect to an exit strategy).
- Where appropriate, offer prospective participants a range of options.
- Be aware of the risks to researchers themselves, as well as to participants and others who may be present during the research, and minimise the potential risks in the research design.
- Show respect for the potential diversity of prospective participants in designing and undertaking the research.
- Pay attention to communication and prepare to meet support requirements in this respect, if necessary.
- Consider consent as an ongoing process.
- Be aware of power relationships in research (e.g. when undertaking research with people in care).
- Listen to participants and do not make assumptions about what participants want.

For further discussion of related issues, see the Preventing Harm in Research and Innovation (Safeguarding) Policy, Research Ethics Policy Notes nos. 2 (Principles of Consent), 3, (Participant Safety and Well-being), and 4 (Principles of Anonymity, Confidentiality and Data Protection), and the following Specialist Research Ethics Guidance Papers:

- Doing research with people with learning disabilities;
- Research involving adult participants who lack the capacity to consent;
- Ethical considerations in research with children and young people; and
- Ethical considerations in research involving older people.

The University of Sheffield
Research Ethics Policy Note no. 7

ADMINISTRATIVE RESEARCH WITHIN THE UNIVERSITY

All research involving human participants, personal data or human tissue which is carried out by, or on behalf of, Professional Services departments of the University (i.e. 'administrative research') is subject to research ethics review (unless an appropriate exception applies; see section 3.1.11 of the Research Ethics Approval Procedure). This also applies to administrative research undertaken within academic departments, faculties or research centres, and aims to guarantee consistency across the full spectrum of the University's activities. It should also be a useful contribution to ensuring that whatever inquiries the University makes are of the highest possible quality.

Procedure aside, administrative research undertaken within, or on behalf of, the University is subject to the same research ethical requirements as academic research undertaken within, or on behalf of, the University. This principle applies whether the work is undertaken in-house, by University staff or students, or contracted out to an external research organisation (such as a market research company, for example).

2 ETHICS REVIEW PROCEDURE FOR ADMINISTRATIVE RESEARCH

The following ethics review procedure applies to research which involves human participants, personal data or human tissue, undertaken within all Professional Services departments. It also applies to administrative research that is undertaken within academic departments/faculties/research centres.

2.1 Is it research?

Since, for administrative work, it is not always clear whether a particular inquiry constitutes research, the first stage is to determine whether or not ethical review will be required. As a general rule, if the findings of an investigation involving human participants and/or personal data are to be disseminated externally (e.g. via an academic publication, conference, or blog post), then the definition of 'research' set out in the General Principles and Statements section of this Policy will be met. Investigations carried out to solely to inform internal audits, service evaluations or reviews will not come under the requirement for ethical review. Should the member of staff who is taking the lead on the work require advice on this, they may contact the Ethics Administrator or the Principal Ethics Contact for Professional Services/administrative research, who may consult with the Chair of UREC in order to decide whether ethics review is necessary.

2.2 Ethics review

The second stage, should it be decided that ethics review is necessary, will involve the member of staff who is taking the lead on the project submitting an ethics application using the online Ethics Application System (refer to the Research Ethics Approval Procedure section of this Policy for full details). NB. For administrative research taking place within an academic department/faculty/research centre, the applicant must specify in the application form that

the review should be undertaken by the 'Professional Services' rather than their home department/faculty/research centre.

Three ethics reviewers will be appointed by the Ethics Administrators for Professional Services/administrative research. A pool of ethics reviewers has been identified from across the Professional Services and includes staff in administrative roles within academic departments/faculties/research centres. Should the reviewers be unable to reach a consensus on the decision, the UREC will undertake an ethics review of the application. The UREC's decision is final.

The University of Sheffield
Research Ethics Policy Note no. 8

USING EXTERNAL RESEARCH ORGANISATIONS

From time-to-time research involving human participants is carried out on behalf of the University of Sheffield by external organisations: market research organisations, private- or public-sector social research organisations, voluntary sector organisations, and so on.

Many of these organisations have their own research ethics guidelines or policies. However, in all cases it is the University of Sheffield's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue (Ethics Policy) that should govern the conduct of the research. These organisations should also be made aware of, and asked to comply with, the Preventing Harm in Research and Innovation (Safeguarding) Policy. The University of Sheffield is the contracting body and the University's research policies apply to any research that is carried out on its behalf. The contract under the terms of which such research is undertaken must stipulate this clearly and unambiguously. Research contractors must be made aware of the policies' details.

Such research must be approved in accordance with the University of Sheffield's Ethics Policy and the details of the research ethics stipulation(s) in the contract with the external organisation should form part of the documentations submitted for ethics review.

In addition to the above, from a data protection perspective, any arrangements with external research organisations must comply with data protection legislation if personal data will be collected and used as part of the work. The contract with the organisation must clearly set out the rights and liabilities of the Data Controller (the University) and the Data Processor (the external organisation). Further guidance is provided by the Information Commissioners' Office (https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/accountability-and-governance/contracts/)

The University of Sheffield
Research Ethics Policy Note no. 9

ARCHIVAL RESEARCH

1 PERSONAL DATA IN ARCHIVES

Accessing Personal Data in Archives

The General Data Protection Regulation (GDPR) enables archives, both public and private, to acquire and preserve records that contain personal data,[1] and provide access to those records to researchers, for 'archiving purposes in the public interest'.[2]

Any researcher who accesses personal data about a living individual, or material that could be used to identify a living individual, must observe data protection laws for 'processing' that data.

Before accessing personal data in archives, researchers may be asked by the archival repository to:

- provide a clear and precise explanation of any exemptions that they are claiming from data protection regulations, or the legal basis on which they plan to process data related to living individuals;
- explain how they will undertake historical research within the specified safeguards;
- sign a declaration or undertaking that they will comply with legislation and not identify living individuals unless in ways provided for by data protection law and its exemptions;
- undertake to comply with any sectoral codes of practice or employer requirements such as gaining ethical approval, where appropriate, through institutional research ethics approval procedures.

Researchers must comply with all requirements and conditions of access that are stipulated by archives in which they wish to conduct research.

Lawful Basis for Processing Personal Data

[1] As detailed in Research Ethics Policy Note no. 1, the University's Research Ethics Policy uses the General Data Protection Regulation (GDPR) definition of personal data:

> "'personal data' means any information relating to an identified or identifiable natural (living) person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person."

[2] The National Archives (TNA), *Guide to Archiving Personal Data* (2018), https://cdn.nationalarchives.gov.uk/documents/information-management/guide-to-archiving-personal-data.pdf.

Anyone processing personal data must identify a lawful basis on which to do so. The University's view is that for the vast majority of research undertaken at the University, including research involving archives, this will be that 'processing is necessary for the performance of a task carried out in the public interest'. This is set out in the University's Privacy Notice: https://www.sheffield.ac.uk/govern/data-protection/privacy/general.

If a 'public interest' basis is applied, a researcher must be able to show that the processing of personal data is necessary, and be able to 'demonstrate there is no other reasonable and less intrusive means to achieve your purpose'.[3]

Special Categories of Personal Data

Data Protection Law generally prohibits the processing of certain 'special' categories of personal data, (previously known as 'sensitive data'). This includes information about:

- racial or ethnic origin;
- political opinions;
- religious or philosophical beliefs;
- trade union membership;
- genetic or biometric data for the purpose of uniquely identifying a natural person;
- health, sex life or sexual orientation.

However, processing of special categories of personal data is permitted if a lawful basis is identified (see above), and an appropriate separate condition for processing special category data exists. The UK Data Protection Act includes historical research as one of these appropriate conditions. (The National Archives *Guide to Archiving Personal Data* notes that 'any research done in an archive repository will be "historical" in its widest sense'.[4]) The processing must 'be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject'.[5]

Exemptions for Research

Where processing personal data for 'scientific or historical research purposes' or 'statistical purposes' would be made impossible or seriously impaired by having to comply, research can be exempted from the GDPR's provisions on data subjects' rights related to:

- the right of access;
- the right to rectification;
- the right to restrict processing; and
- the right to object.

[3] Information Commissioner's Office (ICO), quoted in Royal Historical Society (RHS), *Data Protection and Historians in the UK* (July 2020), p. 14, https://files.royalhistsoc.org/wp-content/uploads/2020/07/19092331/20200707_RHS_Data_Protection_Historians_WEB2.pdf.

[4] TNA, *Guide to Archiving Personal Data*, p. 14.

[5] RHS, *Data Protection and Historians in the UK*, p. 15.

Principles for the Processing of Personal Data

Beyond the exemptions specified above, researchers processing personal data for 'scientific or historical research purposes' or 'statistical purposes' must still comply with six principles for the processing of personal data that are at the heart of the GDPR. The six principles are that personal data must be:

- processed lawfully, fairly and in a transparent manner;
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing is allowed for historical research purposes because it is not considered 'incompatible with the initial purposes';
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed;
- accurate and, where necessary, kept up to date; (in the case of archiving or historical research, data does not need to be kept up to date in the usual sense intended for personal data; as the National Archives *Guide to Archiving Personal Data* comments, 'archives are concerned with historical integrity rather than current accuracy'[6]);
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; (the Information Commissioner's Office (ICO) states that data can be kept 'indefinitely' when used solely for historical research purposes, as long as safeguards are in place to protect individuals[7]);
- processed in a manner that ensures appropriate security of the personal data. This includes protection against unauthorised or unlawful processing; accidental loss, destruction or damage; and using appropriate technical or organisational measures to protect data (including pseudonymisation if appropriate).

Research Ethics Approval Procedure

[NB. The reference in this Policy Note to 'publicly accessible archives or formally constituted repositories accessible to scholars' is intended to cover archives where there is a reasonable expectation that the collections have been curated in line with data protection requirements; it does not include open online platforms providing access to datasets uploaded by users. If in doubt, advice should be sought from the department Principal Ethics Contact and/or the University Research Ethics Committee.]

In line with norms for archival research across the higher education sector, archival research in either a publicly accessible archive or in a formally constituted repository accessible to scholars, that is undertaken for 'scientific or historical research purposes' or 'statistical purposes', and that is undertaken on a lawful basis ('in the public interest'), does

[6] TNA, *Guide to Archiving Personal Data*, p. 19.

[7] ICO, quoted in RHS, *Data Protection and Historians in the UK*, p. 12.

not require ethics review and approval via the Research Ethics Approval Procedure, unless this is required by the archive repository itself.

Though most archival research involving 'personal data' thus does not require ethics review and approval via the Research Ethics Approval Procedure, researchers must comply with all ethical and data protection requirements specified by the archive repository they are accessing, and must comply with their legal data protection responsibilities, including the six principles for the processing of personal data outlined above.

All archival research that involves accessing personal data in archival materials (for instance private family collections) that have not been deposited in either a publicly accessible archive or in a formally constituted repository accessible to scholars does require ethics review and approval via the Research Ethics Approval Procedure.

Further Guidance

As the National Archives *Guide to Archiving Personal Data* notes, 'any research done in an archive repository will be "historical" in its widest sense'.[8] Researchers conducting archival research involving personal data can also therefore consult the Royal Historical Society guidelines on *Data Protection and Historians in the UK* (2020), from which much of the guidance above has been drawn.

2 OTHER ETHICAL ISSUES IN ARCHIVAL RESEARCH

Much archival research relates to individuals who are not living and, therefore, does not involve 'personal data' as defined under GDPR. This does not, however, mean that there are no ethical issues involved in this kind of archival research.

Formally-constituted publicly-accessible archives are generally straightforward, in that the material in them can be considered to be in the public domain already. Even here, however, there may be issues about ownership, publication and confidentiality that require explicit agreements.

The following ethical issues should be considered when undertaking research in archival materials (for instance private family collections) that have not been deposited in either a publicly accessible archive or in a formally constituted repository accessible to scholars.

First, there is a responsibility to treat ethically the owner(s) or controller(s) of the archive. Explicit agreements should ideally be entered into, and recorded, about:

- the uses to which archival material will be put;
- if relevant, the nature of any anonymising strategies that will be employed;
- the ownership and copyright of the material; and
- the rights of approval of publication (if any) of the owner(s) or controller(s).

[8] TNA, *Guide to Archiving Personal Data*, p. 14.

There may, depending on circumstances, be other matters to consider in this respect. It is important, and in the best interest of all parties, that factors such as these be dealt with explicitly and recorded appropriately.

Second, the competence and legal right of ownership (or control) of those with whom access to archival material is negotiated should not merely be assumed. It is a researcher's responsibility to satisfy themselves of the propriety and legality of their actions in this respect.

The University of Sheffield
Research Ethics Policy Note no. 10

RETROSPECTIVE RESEARCH ETHICS REVIEW

It is fundamental to the spirit of the University Research Ethics Policy that research involving human participants, human tissue or personal data should not begin before research ethics review has taken place, according to the Research Ethics Approval Procedure, and ethics approval granted. Retrospective ethics review is, therefore, not permitted. It is the responsibility of the principal investigator or, in the case of a student project, the supervisor, to ensure that ethics review is undertaken in good time. There are no exceptions to this principle.

However, there may be circumstances in which there is legitimate uncertainty about when research begins (or has begun). In particular, scholars may accidentally, or unexpectedly, come across materials or events that subsequently become of research interest (i.e., they could be used as data within research).

The following examples may serve to illustrate the kinds of circumstances in which this may, with the best of intentions, happen:

- Attendance at a public occasion generates notes and observations that, subsequently, contribute to the framing of a research problem. For the sake of illustration, the occasion in question might, for example, be a political meeting, an academic conference, or a sporting occasion.
- An historian may come across documents that deal with living individuals and which set off a train of research thought. The expression 'come across' can cover a variety of eventualities: someone may send them, unsolicited, to the scholar concerned, for example, or the researcher may find them in an archive while investigating another, unrelated matter.
- A routine Internet search for material of interest with respect to ongoing research, or even undertaken for unfocused curiosity, may throw up something unexpected that stimulates the development of another line of research.
- Data collected as part of routine student module evaluations may show some interesting trends which the module leader would like to develop into a publishable piece of research.

These examples are simply chosen to illustrate the role of serendipity in the genesis of research, and do not exhaust the possibilities.

Taking the first paragraph of this Research Note completely literally it might be thought that in all four of the above cases the initial material would be unusable as data, because it was noted or collected prior to ethics approval.

However, it is not the purpose of the Policy to discourage or prevent ethically defensible research from taking place. So, in cases such as the above, as soon as the researcher in question decides either (1) to develop a research project on the basis of the original materials or (2) to publish an account or analysis of the material in question, without further research, ethics review must take place immediately. No further work on the material will be

permissible until ethics review has taken place. The research ethics application must make it clear that research ethics approval is being sought for existing material, that might already be in the researcher's possession, to be used in research, and that retrospective research ethics approval is not being sought.

These limited exceptions cannot be used to permit retrospective ethics review for a project that could, and therefore should, have been reviewed through the normal procedure. Therefore, applications of this, exceptional, kind must initially be referred to the University Research Ethics Committee (UREC), together with details of how the materials were originally generated, and the original intention of these materials. UREC will determine whether it would be legitimate for a research ethics application to be made for these materials to be used for research and thus, decide whether they should proceed to ethics review within the department concerned. Only once this process has been undergone, and research ethics approval has been obtained, can research on the materials commence.

The University of Sheffield
Research Ethics Policy Note no. 11

RESEARCH INVOLVING HUMAN TISSUE

1 Overview

In England, Wales and Northern Ireland, the use of human tissue for research purposes is legally regulated by the Human Tissue Act 2004 (HTAct), which covers the use of tissue classed as 'relevant material' from both the living and the deceased. In Scotland, the use of human tissue is regulated by the Human Tissue (Scotland) Act 2006 (HTAct Scotland), and covers the use of organs, tissue and tissue samples from the deceased.

Section 2 of this Policy Note covers the key legal, regulatory and ethical review requirements for research involving 'relevant material' under the HTAct. Researchers undertaking research involving the use of human tissue in Scotland should seek further guidance regarding the HTAct Scotland (sources of further information and training are set out in section 4 of this Policy Note).

It should be noted that, in the whole of the UK, the collection of tissue for research purposes (i.e. any material consisting of or including human cells) from any past or present users of NHS or adult social care services will require ethical review by an NHS Research Ethics Committee (NHS REC). Additionally, previously collected tissue from which individual past or present users of NHS and adult social care services are likely to be identified by the researchers, will require ethical review by an NHS REC.

Research involving human tissue which does NOT come under the requirement for ethical review by an NHS REC, must meet the University's expectations for ethical review; these are set out in section 3 of this Policy Note. This includes research taking place outside the UK, research which does not involve 'relevant material', or research which involves collection of tissue from 'healthy volunteers' (either for immediate processing or where the tissue will be stored in premises licensed by the Human Tissue Authority (HTA)).

The regulatory framework on human tissue and cells is in a state of development, with continuing revisions and updates of the guidance by regulators to ensure that the regulations keep abreast of fast-moving technology. If a researcher is in any doubt as to whether their research project requires ethical approval from any of the bodies referred to in this document, or the University's Ethics Review Procedure, they must seek guidance from UREC.

2 Research involving the use of 'relevant material' under the HTAct

The HTAct makes it a criminal offence to engage in various activities involving human tissue and cells, such as storage, without a licence (issued by the HTA), *unless* the tissue/cells are being used in a specific research project that has been authorised and approved by a 'recognised ethics review committee' (RERC). Currently, all Research Ethics Committees within the NHS or Health and Social Care in Northern Ireland (NHS RECs) are recognised for this purpose.

University research ethics committees are not 'recognised' committees for this purpose and researchers undertaking research which falls under the HTAct must check whether they need to seek approval from an NHS REC prior to commencing research, using the Health Research Authority's ethics decision tool. University ethics approval may be obtained for studies

involving human tissue and cells that do not require NHS REC approval, providing donor consent is obtained in line with the HTAct, AND the tissue/cells are immediately processed (i.e. not stored) OR are stored on HTA licensed premises.

The types of human tissue and cells that are covered by the HTAct are referred to as 'relevant material'. Relevant material covered by the Act includes materials consisting of or including cells that have come from a human body, whether living or dead, including body parts, organs and human cells.

Established cell lines are not relevant material, but primary cell cultures are. A primary cell culture becomes an established cell line when the cell cultures have divided to an extent that all the original cells have been replaced by new cells created within the culture. Storage of established cell lines for research does not require a licence, nor does research using cell lines require ethical review (except in the case of human embryonic stem cell lines – see paragraph relating to HFEA requirements below).

Human tissue xenografts are classed as 'relevant material' as they will contain cells that have come from human bodies; however, once they have been transplanted into another species the human tissue will be integrated and become a part of the recipient species; this is no longer considered storage of 'relevant material' and will not require a HTA licence.

The storage and use of human reproductive cells and embryos outside the body is regulated separately, by the Human Fertilization and Embryology Authority (HFEA), under the Human Fertilization and Embryology Act (2008). All research involving human reproductive tissue requires a research licence from the HFEA and must undergo ethical review. The use of stem cell lines, derived from human embryos (human embryonic stem cells), in research requires project-specific approval from the MRC UK Stem Cell Bank Steering Committee to ensure that research performed is in keeping with HFEA Regulation. The process of obtaining approval requires an institution signature (from the Head of Department/Dean) which states the institution will abide by the "Code of Practice for the Use of Human Stem Cell Lines".

The HTAct does not cover hair and nails from a living person. However, the HTAct does make it a criminal offence to hold human tissue - including hair, nails, and gametes (i.e. cells connected with sexual reproduction) – for the purpose of DNA analysis, without the consent of the person from whom the tissue or cells came (or of those close to them if they are deceased). Medical diagnosis and treatment and criminal investigations are excluded.

It is important to distinguish between the *licensing* by the HTA of premises as approved storage facilities for human tissue and the *ethics approval* of research involving human tissue.

Ethics approval by a RERC (i.e., an NHS REC) for human tissue research is a legal requirement under the HTAct in the following circumstances:

- if a specific research project involves the storage or use of relevant material on premises without a licence from the HTA to store relevant material for scheduled purposes;
- if the research involves the storage or use of relevant material taken from a living person without their consent for the research (in which case, in addition to ethics approval, the research must be conducted such that the donors are not identifiable to the researchers); or
- if the research involves the storage or use of bodily material from a living person with

the intention of undertaking DNA analysis without consent for such analysis (in which case, in addition to ethics approval, the research must be conducted such that the donors are not identifiable to the researchers).

Relevant material can be obtained for research purposes in three ways:

Firstly, de-identified relevant material can be obtained from a human tissue bank that is licensed by the HTA to house tissue for unspecified research. The research purpose(s) must, however, be specified prior to the use of the tissue or cells, and the research must comply with the human tissue bank's conditions, which will include:

- provision of evidence of independent scientific approval;
- compliance with the terms of the donor's consent;
- anonymisation of the relevant material at the point of release;
- compliance with a Materials Transfer Agreement; and
- compliance with requirements for managing the relevant material at the end of the study (e.g. destruction or return to the tissue bank)

If the human tissue bank does not have generic research tissue bank ethics approval from an NHS REC, then the samples to be obtained must be stored on HTA-licensed premises AND/OR project-specific ethics approval from an NHS REC must be sought.

If identifiable relevant material is required from the human tissue bank, project-specific ethics approval from an NHS REC **must always be sought**, regardless of whether the tissue bank itself has generic research tissue bank approval.

Secondly, relevant material can be obtained by application to an NHS REC for ethics approval for a specific research project that will include the collection of human tissue or cells from past or present users of NHS/adult social care services.

At the end of an NHS REC-approved research project the relevant material must be handled in one of the following ways:

- deposited in a human tissue bank licensed by the Human Tissue Authority (or returned to the tissue bank from which it was originally obtained);
- transferred to HTA-licenced premises such as the Sheffield Biorepository for storage (additional NHS REC approval will be required to use the tissue);
- used for a new research project, after new NHS REC ethics approval has been obtained;
- or destroyed in line with the Human Tissue Authority's Codes of Practice and Standards, Code E: Research.

One of these steps **must be taken before** the expiry date of any existing NHS REC approval; if the material needs to be held beyond the expiry date to allow the same project to continue, an extension to the NHS REC approval must be sought BEFORE the expiry date of the original approval is reached.

Thirdly, University ethics approval can be sought to obtain relevant material from 'healthy volunteers' (i.e. individuals identified and recruited outside of the NHS/adult social care services), providing the relevant material is immediately processed (i.e. not stored) OR is

stored on HTA licensed premises. Appropriate informed consent must be sought, and this should be checked as part of the ethics review process.

3 Research involving the use of human tissue which is not regulated by the HTAct, or which does not require ethical review by an NHS REC

The ethical review requirements for a number of scenarios which do not come under the HTAct, or which do not require review by an NHS REC are set out below.

[NB. For all projects involving human tissue which are classed as research by the NHS/Health Research Authority (HRA) (including those taking place in Scotland), the NHS ethics decision tool (http://www.hra-decisiontools.org.uk/ethics/) should be checked to verify whether ethics approval from an NHS REC is required.

In addition, any studies involving the storage of 'relevant material' in England, Wales or Northern Ireland (including imported material) will need to store the material under a HTA licence, unless the project has received specific NHS REC ethics approval [note that under the HTAct, import of relevant material includes material moved from Scotland to England, Wales or Northern Ireland]. Furthermore, if the human tissue to be used for the research includes human reproductive cells and embryos outside the body, a licence will be required from the Human Fertilisation and Embryology Authority (HFEA) and further advice should be sought].

a. Human tissue collected outside the UK for research undertaken outside the UK

For projects where human tissue samples are to be collected and used in research outside the UK, appropriate ethics approval must be sought for the project to at least the standard expected for ethical review at the University of Sheffield, and appropriate informed consent must be sought.

If ethics approval will be obtained in the relevant country/ies, an assessment of the ethics process(es) must be undertaken by UREC to ensure that they are suitably robust, in line with the section of the Ethics Policy concerning Alternative Ethics Review Procedures.

If deemed to be robust, the researcher must create a new ethics application in the online Ethics Application System, selecting the option that confirms that the research is taking place outside the UK. They should then follow the process for submitting copies of (1) the research ethics application form (which should name them as a collaborator and/or include supporting information from the collaborating researcher(s) confirming the TUoS researcher's involvement in the project) and (2) a letter from the institution's ethics body confirming its ethics decision with respect to the project.

If not deemed to be robust (or if no local ethics approval is being sought), ethics approval must be sought via the standard University of Sheffield ethics review procedure; informed consent arrangements must be detailed as part of the application.

For projects where existing samples will be obtained from collaborating institutions/commercial providers outside the UK, for use within the UK, see scenario (d) below.

[NB. If 'relevant material' collected outside the UK is to be imported into the UK for

research (including importing from Scotland), it must be stored in HTA licensed premises. If this is not possible, the project must have specific ethics approval from an NHS REC. If embryonic stem cells are imported into the UK for research, project-specific approval from the MRC UK Stem Cell Bank Steering Committee must be obtained, and if these cells are to be used for potential human application, they must be imported under an HTA import licence and stored in HTA licenced premises. Similarly, tissues and cells that form the starting material for Advanced Therapy Medicinal Products (ATMPs) must also be imported under an HTA import licence].

b. Human tissue classed as 'relevant material' is collected from healthy volunteers in the UK for use in research in the UK

For projects where human tissue samples classed as 'relevant material' are to be collected from 'healthy volunteers' in the UK (i.e. individuals identified and recruited outside of the NHS/adult social care services), and are immediately processed (i.e. not stored) OR are stored on HTA licensed premises, University of Sheffield ethics approval will be required. Appropriate informed consent must be sought/evidenced, and this should be checked as part of the ethics review process.

[NB. If 'relevant material' is NOT to be immediately processed or stored on HTA-licensed premises then the project must have specific NHS REC approval. If 'relevant material' (e.g. blood) is only being collected in order to immediately undertake tests and then destroy it the same day, or to process it to render it acellular, so that acellular material can be used for the research and any cellular material destroyed, then this is not 'storage'. The requirement for an HTA licence or NHS REC approval no longer applies and University ethics approval would be sufficient].

c. Human tissue not classed as 'relevant material' by the Human Tissue Act is collected in the UK for use in research in the UK

For projects where human tissue not classed as 'relevant material' by the HTAct will be collected for research from 'healthy volunteers' (i.e. individuals identified and recruited outside of the NHS and adult social care services), normally University of Sheffield ethics approval would be required.

However, if the non-relevant material to be collected includes human reproductive cells and embryos outside the body, a licence will be required from the Human Fertilisation and Embryology Authority (HFEA) and further advice should be sought.

Additionally, if non-relevant material will be collected from individuals identified via the NHS/adult social care services as users of these services, then ethics approval from a NHS REC will be required. The NHS ethics decision tool (http://www.hra-decisiontools.org.uk/ethics/) should be checked to verify whether ethics approval from an NHS REC is required.

d. Human tissue collected previously is used for a new research project in the UK

i. Obtaining de-identified human tissue from tissue banks

If a researcher is obtaining de-identified tissue samples (whether 'relevant' or 'non-relevant' material) from an HTA-licenced research tissue bank in England, Wales or Northern Ireland which has generic ethics approval from an NHS REC to issue samples, then the researcher does not need to seek further ethics approval.

If obtaining de-identified tissue samples which will be provided by an HTA-licenced research tissue bank in England, Wales or Northern Ireland which has NOT received generic NHS REC approval to issue samples, then providing the samples are not 'relevant material', University of Sheffield ethics approval will be required. Appropriate informed consent must be sought/evidenced along with confirmation that appropriate ethics approval was in place for the original sample collection (these points should be checked as part of the ethics review process).

[NB. If the samples to be provided are 'relevant material' then they must be stored on HTA-licenced premises if University ethics approval is being sought, OR project-specific NHS REC approval must be sought instead of University ethics approval. Additionally, if no informed consent is in place, then NHS REC approval must be sought even if the samples will be de-identified].

ii. Obtaining de-identified human tissue from other sources

If obtaining de-identified tissue samples which are not relevant material from other sources either within or outside the UK (e.g. an earlier research project, a collaborating institution or a commercial provider), University of Sheffield ethics approval will be required. Appropriate informed consent must be sought/evidenced along with confirmation that appropriate ethics approval was in place for the original sample collection (these points should be checked as part of the ethics review process).

[NB. If the samples to be provided are 'relevant material' then they must be stored on HTA licensed premises if University ethics approval is being sought, OR project-specific NHS REC approval must be sought instead of University ethics approval. Additionally, if no informed consent is in place, then NHS REC approval must be sought even if the samples will be de-identified. If embryonic stem cells are imported into the UK for research, project-specific approval from the MRC UK Stem Cell Bank Steering Committee must be obtained, and if these cells are to be used for potential human application, they must be imported under a HTA licence and stored in HTA-licenced premises].

e. Human tissue samples are collected and/or existing identifiable tissue samples are used in the UK for work not classed as 'research' by the NHS/HRA (e.g. service evaluation/audit)

For UK-based projects where human tissue (whether 'relevant' or 'non-relevant' material) will be collected for work classified as research by the University (according to the definition of research set out in the Research Ethics Policy), but not by the

NHS/HRA (as established via the HRA's research decision tool: http://www.hra-decisiontools.org.uk/research/), University ethics approval will be required.

[NB. If tissue is 'relevant material' and is to be stored for 'scheduled purposes' then this must be on HTA-licenced premises]

4 Further information and training expectations

Any researcher working with human tissue in the UK must undertake training on the HTAct and its Codes of Practice, and should ensure that they renew this training on a regular basis. The HRA provides an e-learning module on Research Involving Human Tissue:

https://www.hra.nhs.uk/planning-and-improving-research/learning/e-learning/.

The HTA Codes of Practice for Research are key sources of information for researchers; in particular Code of Practice A - Guiding principles and the Fundamental Principle of Consent and Code of Practice E – Research:

https://www.hta.gov.uk/guidance-professionals/codes-practice

The Medical Research Council also provides a number of e-learning courses relating to human tissue in research, including the requirements which apply in Scotland: https://byglearning.com/mrcrsc-lms/course/index.php?categoryid=1.

The University of Sheffield
Research Ethics Policy Note no. 12

RESEARCH INVOLVING ILLEGAL ACTIVITIES

This is a complex area. There is a long tradition of social science research into illegal activity that has enriched public debate about crime and a range of other public issues. Similarly, researchers in psychology or medicine, for example, might in the course of their research learn about criminal activity. But what is the legal and ethical position of the researcher in such circumstances?

1. LEGAL RESPONSIBILITIES

Researchers have the same legal obligations that they would have in any other context, as citizens or legal residents. As a private member of society, there is, however, no *general* legal obligation in the United Kingdom to report to the relevant authorities all illegal activity that one observes or learns about.

However, there may be *moral* obligations to report in the following circumstances:

1. It may be a requirement of access, imposed by any relevant gatekeeper;
2. It may be a condition of research funding;
3. It may be a tradition within the specific discipline and/or research context (for example, in criminology there is a tradition of warning convicted offenders that confidentiality will be breached should the participant reveal a previously undetected offence); and, perhaps most importantly;
4. The researcher might see certain circumstances as requiring disclosure as a matter of personal morality and/or professional ethics and/or safeguarding.

Researchers working outside the UK should ensure that they find out about the legal framework in the country/ies in which they will be carrying out the research, including obligations for reporting of information regarding illegal activities in the relevant jurisdictions. They should consider carefully how this may impact upon the implementation of their project, and discuss how they will approach this as part of their ethics application. Further guidance on carrying out research outside the UK can be found in the Specialist Research Ethics Guidance Paper on Ethical International and Intercultural Research].

The important thing to emphasise here is that researchers MUST be clear to their participants from the start as to the circumstances in which they will breach the confidentiality of the data that the participant provides.

The definite obligations to disclose that exist in United Kingdom law relate to child protection offences such as the physical or sexual abuse of minors, the physical abuse of vulnerable adults, money laundering and other crimes covered by prevention of terrorism legislation. These obligations are concerned primarily with serious and immediate harm to others.

These obligations aside, research is not covered by any legal privilege. Although there has been a long tradition of academic research into illegal activities, the courts have never considered

whether or not one might lawfully refuse to disclose confidential information on 'public interest' grounds – i.e. on the basis that the benefits of completion of the research to society at large outweighs any harm caused by the failure to report individual offences.

That said, researcher knowledge of illegality has not historically and is not (at the time of writing) seen as grounds for rendering a researcher liable for prosecution; this does not, however, mean that it never will be. Researchers and ethics committees are encouraged to keep abreast of developments in this area.

Lastly, it should be remembered that there is a huge difference in the evidential standards of social science research, for example, and the sterner demands of a court of law, particularly in criminal proceedings. Unless a researcher has actually seen an offence being committed, or can offer other hard proof of criminality - such as knowledge of the location of proscribed drugs, illegal weapons or stolen goods, for example - then most information that is garnered as research data would probably fall into the category of hearsay, if tested in court. At best it would be likely to be considered as 'intelligence' rather than admissible evidence.

Disclosure to the Police would only generally be useful for the prosecution of the (alleged) offender-participant if it led to the discovery of clearer evidence of criminal wrongdoing, and the researcher (and ethics committee) in question ought to:

1. Factor this into any decision as to when to breach confidentiality; and
2. Ensure that prospective participants are fully informed of the circumstances in which confidentiality will be breached, and what the researcher will do to avoid having to disclose confidential information, as mentioned above.

2. RESPONSIBILITIES TO THE UNIVERSITY

As employees of the University of Sheffield, researchers have a professional duty to refrain from doing anything that would bring the University into disrepute. However, the issue of disrepute is neither obvious nor straightforward. What counts as 'disrepute' is not settled, and will depend very much upon the individual circumstances of the research project in question. These issues are particularly emphasised by research into illegal activities, such as 'joy-riding' and drug dealing. On the one hand, the value of understanding these forms of criminality more fully, and the concomitant utility of such research for those drafting better laws or designing more effective policies, is likely to boost the perceived value of the research, and thus the reputability of the University. However, on the other hand, if such research seems to condone the activity in question, either for the duration of the project or in general, then that could be seen as research tending to bring the University into disrepute. The issue, in other words, is very much a matter of context, and is often in the eye of the beholder.

The researcher and their host department ought to be very clear, and very careful, about making claims using data drawn from illegal activities. Researchers should generally refrain from: (a) participating in illegal activities themselves, and (b) encouraging others to participate in illegal activities, for the purposes of providing research data.

3. SUMMARY POLICY AND GUIDANCE

As a general principle, researchers, as University employees and as citizens or legal residents of the United Kingdom, have a responsibility to report to the relevant authorities any actions or planned actions, discovered during the course of research, which they believe are likely to result in serious and immediate harm to others. Beyond that, however, much will depend upon a researcher's own moral compass and judgment. Researchers working outside the UK must find out about the legal framework in the country/ies in which they will be carrying out the research.

Researchers have responsibilities to participants, too, as outlined in this Policy. Additionally, researchers should consider the University's Preventing Harm in Research & Innovation Policy alongside this Policy Note. Participation in research should not place people in greater hazard than they would otherwise be. Researchers should, if they anticipate that they may become aware of illegality, tell actual and potential research participants about the requirements of the Policy, as spelled out above, and about the nature and limits of whatever confidentiality they feel they can offer. This should be part of negotiations about consent.

Researchers also have a responsibility to themselves and their research collaborators, to avoid, where possible - and it may not always be possible - acquiring information that is likely to prove dangerous, compromising or otherwise problematic in the senses discussed in this Policy Note. If possible, erring on the side of caution and avoidance is a sensible basic principle. Again, the University's Preventing Harm in Research & Innovation Policy should be considered alongside this Policy Note.

In observing the above responsibilities, caution is particularly indicated with respect to what is recorded audio-visually, digitally and in writing.

Finally, a principled and defensible ethics approval procedure is impossible in the absence of proper information. If a researcher anticipates encountering any of the issues discussed in this Policy Note, s/he must disclose this in the ethics approval application. If such issues are encountered after the initial ethics approval, the researcher should approach their departmental Principal Ethics Contact for advice.

The University of Sheffield
Research Ethics Policy Note no.13

RE-USE OF EXISTING DATA IN RESEARCH

Researchers have a responsibility to protect participants from any potential harm or distress that may arise from their participation in a research project. Therefore, researchers wishing to use existing datasets for a new research project (whether the original data were collected for research, clinical or other purposes) need to consider the dignity, rights, safety and well-being of those who provided the data, including whether information may need to be provided to those individuals about the new project, and what kind of ethics approval and/or consent/permissions they may need to obtain. The University's Preventing Harm in Research and Innovation (Safeguarding) Policy should also be considered.

There is likely to be minimal harm to participants if their data has been truly anonymised, via the removal of any identifying data (not just names, but dates of birth, addresses, postcodes, phone numbers, user IDs, IP addresses etc.). However, consideration should still be given to whether the original participants (or relevant groups of individuals) would be likely to object should they become aware of the aims and purpose of the new project (this would need to be considered on a case by case basis).

Ethical approval is therefore NOT required for research that only involves existing data that has been *robustly* anonymised, such that the original providers of the data cannot be identified, directly or indirectly, by anyone (i.e. it does not involve personal data). Research involving existing data which may contain personal identifiable data will therefore normally require ethics approval, unless an appropriate exemption applies (see section 1.1 of the Research Ethics Approval Procedure and Research Ethics Policy Note no.9 'Archival Research'). Researchers are encouraged to use the self-declaration process available via the online Ethics Application System, to ensure that they have covered all relevant considerations in using existing data as part of their project, and to ensure that this process has been appropriately documented.

Informed consent is not a legal requirement for using truly anonymised data. However, from an ethical standpoint, the researcher should seek informed consent where possible for the re-use of data for a new research purpose either by contacting the participants directly, or by requesting evidence from the original researcher/data provider to confirm that consent for the data to be used for secondary research purposes has been obtained. In the latter case the researcher should obtain a copy of the terms of the original consent so that the data can be used in line with the original consent.

If this is not possible then, in general, providing that the data has been robustly anonymised, then it is acceptable for the data to be used for a secondary research purpose, even if consent for secondary research (or primary research in the case of clinical/other data) was not originally sought. However, if consent had been sought for secondary research, but not been granted by a participant, then that participant's data can never be used.

Researchers should be aware that, even when they have sought to anonymise data for secondary analysis, there is still a risk that the original participants could become identifiable, even within large scale data sets - perhaps because they have distinctive characteristics (e.g. families with large numbers of children may stand out in cohort studies) or because a method of analysis combines variables in ways that identify small groups within

a larger sample. In such cases, the data should be considered to be pseudonomised, and would still be classed as personal data, thus requiring ethical approval, and requiring compliance with data protection legislation.

The UK General Data Protection Regulation (GDPR) sets out specific obligations relating to the information that should be provided to the original data subjects when using re-data for a new purpose, unless certain circumstances apply – for example if re-contacting the participants is impossible or would involve disproportionate effort. For further guidance, refer to the Specialist Research Ethics Guidance paper 'Principles of Anonymity, Confidentiality and Data Protection'.

Researchers should also be aware that, where datasets containing personal data are obtained from an external company or organisation, data may not have been 'provided' by people directly and with their knowledge (e.g. mobile phone data, loyalty card data, location data, internet activity logs). Researchers may gain access to such data to analyse it on the external organisation's behalf, and in some cases the analysis might be research-led, whilst in other cases it may be driven by the needs of the organisation (e.g. where the researcher is acting in a consultancy role).

Ethics approval would be required for any work using personal data obtained from an external organisation that falls under the definition of research set out in the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, unless an appropriate exemption applies (see section 1.1 of the Research Ethics Approval Procedure and Research Ethics Policy Note no.9 'Archival Research'). Additionally, the researcher must consider the requirements of data protection legislation, as mentioned in the above paragraphs. As part of the ethical review of such research, the applicant and reviewers should consider the ethical implications of how the data was generated (e.g. participants' potential lack of awareness of their data being used for research), as well as the use to which the analysis is to be put by the external organisation. The researcher should also check whether the external organisation is complying with relevant data protection legislation in collecting, processing and sharing the data.

In addition, it should be noted that, even if data from an external organisation has been de-identified when passed to the researchers, the results of the researchers' analysis might be re-identifiable by the organisation (e.g. via the use of a unique identifier), and may be used to do things that might be deemed unethical by many people (e.g. the identifiable results could potentially be sold on to other companies). If it is likely that the external organisation will be able to re-identify participants from the analysis, then ethical approval should be obtained, even if the researchers will not have access to the personal data themselves.

Finally, all researchers are strongly encouraged to consider the possibility of secondary research and data sharing at the outset, before the primary data collection begins, and to build this into the informed consent process. As such, where a researcher plans to use the data for secondary research (or to share the data, e.g. via a research data repository, for use by other researchers), then they should include details of this in the information given to potential participants, and include an appropriate section on the consent form. The UREC's Information Sheet Guidance and Consent Form Example provide suggested text for informing participants about potential future uses of data and for seeking appropriate consent.

UREC-approved providers of research datasets

A number of organisations provide access to datasets for research purposes. The UREC has approved a number of these providers, meaning that data obtained from them can be used for secondary research purposes without explicit informed consent from the participants, even if the dataset contains personal data (NB. it should be noted that ethics approval should still be obtained if personal data will be accessed). This is due to the fact that they require the researcher to follow a series of robust procedures to gain access to the data, and often require the researcher to comply with a number of specific requirements (e.g. following the terms of any original consent).

A list of UREC-approved organisations can be accessed here: http://www.sheffield.ac.uk/polopoly_fs/1.670012!/file/URECApprovedDataProviders.docx.

The UREC considers the merits of such arrangements on a case-by-case basis; researchers wishing to establish whether data obtained from a particular provider, but not already on the above list, may be used without informed consent, should provide details to the Secretary to the UREC.

Governing Principles and Procedural Steps for the Transfer of Research Data which relates to human participants between Principal Investigators within The University of Sheffield

The University has developed guidance for those wishing to share research data with other researchers internally, to ensure that ethical and legal requirements are met. This guidance can be found here:

http://www.sheffield.ac.uk/polopoly_fs/1.670014!/file/RDMTransferSENATEapprovJun16.doc

The University of Sheffield
Research Ethics Policy Note no. 14

RESEARCH INVOLVING SOCIAL MEDIA

1. BACKGROUND

Social media are communication tools that allow users to share information and communicate online. The content that they create may be publicly available (although it should be noted that social media users may not be aware that this is the case), or access may be restricted to specific individuals or members of a group or community. Examples of social media platforms include Facebook, X (formerly Twitter), Weibo, blogging sites (e.g. Wordpress), video sites (e.g. Youtube), online Instant Messaging services (e.g. Whatsapp), online dating services (e.g. OK Cupid, Grindr), discussion forums etc.

The data generated by users of these tools is a rich data source that is used by researchers across sectors. Social media data includes:

- content that users create (e.g. a comment, Tweet, video, blog post etc.)
- data that records users' engagement with content and other users (e.g. likes, shares, retweets, followers, friends, comments etc.)
- other user data that is collected by the social media company, possibly without the user necessarily being aware that this data is collected (e.g. data on the location of users)
- personal data (i.e., data that are identifiable to individuals, e.g., names, user ids, photographic images)

Depending upon the nature of the research, social media might be used for different purposes e.g.

- Observing social media users to gain insight into a social or socio-technical phenomenon
- Using social media data to develop and test a new tool (e.g. a new interface for visualising social media content related to a particular topic)
- Recruitment of, and/or engagement with, research participants, in order to collect research data

Where social media, and/or data obtained from social media, are to be used for research purposes, ethical approval must be gained prior to collecting and analysing data. This requirement includes the use of secondary datasets containing data derived from social media platforms, in which the original posts are provided, and/or information is provided which may enable the original posts and/or social media users to be identified. Anonymous datasets in which no individual posts are provided, and from which no individual social media users are identifiable, may be used without ethics approval. In such cases, researchers are advised to complete an ethics self-declaration to record their consideration of the need for ethics approval.

Additional restrictions and requirements apply to the collection of data within Instant Messaging platforms; these are set out in the University's policy on the use of Instant Messaging Platforms in Research, Innovation and Knowledge Exchange.

Social media users are defined as **human participants** if you are observing them or using their data for research purposes

Most social media data is defined as **personally identifiable data** under the General Data Protection Regulation.

All research involving social media data therefore requires ethical approval.

Due to the complex and evolving nature of social media platforms, it is not possible - or desirable – to provide strict rules regarding the ethical use of social media platforms and data. However, a number of organisations and networks have published guidelines and frameworks for assessing the ethical issues related to research using social media which the UREC recommends for further reading. For example:

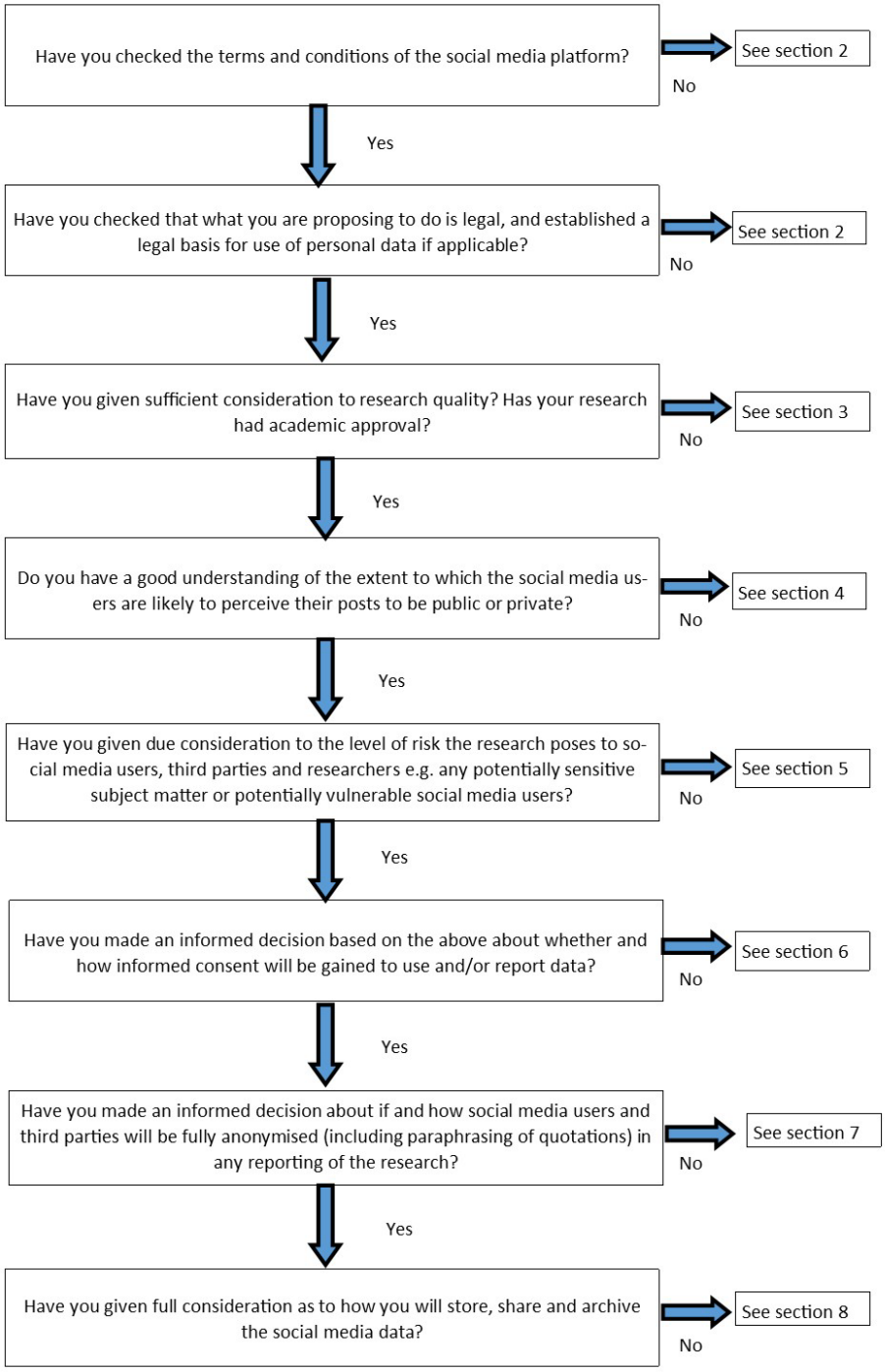
- AOIR Association of Internet Researchers (2019). Internet research: Ethical Guidelines 3.0. Available at: https://aoir.org/reports/ethics3.pdf.
- British Psychological Society (2021). Ethics Guidelines for internet-mediated research. Available at: https://www.bps.org.uk/sites/www.bps.org.uk/files/Policy/Policy%20-%20Files/Ethics%20Guidelines%20for%20Internet-mediated%20Research.pdf
- ESRC (n.d.) Internet-mediated research. Available at: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/frequently-raised-topics/internet-mediated-research/
- Townsend L. and Wallace C. (2016). Social Media Research: a guide to Ethics. Available at: https://www.gla.ac.uk/media/Media_487729_smxx.pdf

This policy note is based upon a review of these documents. Ethical issues raised in four social media scenarios were also discussed in depth by participants in a UREC workshop (summer 2016). The scenarios and notes from these discussions are available on the UREC website, and aim to help researchers think about the ethical issues related to social media research: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/educationresources/social_media_workshop_july_16

UREC recognise that there are many grey areas in social media research and suggest that researchers contact the UREC should they need advice on a specific research project.

Below, we provide a framework for addressing ethical considerations in social media research, which directs researchers to the relevant sections of this document.

Framework for addressing ethical considerations in social media research (Adapted from Townsend and Wallace, 2016)



2. IS IT LEGAL?

Before conducting any research using social media it is important for the researcher to familiarise themselves with the Terms and Conditions of the social media platform, and make sure that what they are proposing to do is allowed by the site. Terms and Conditions of social media platforms change regularly, so researchers need to make sure that their understanding is up to date.

Social media platforms such as Facebook and X also make the data that users have posted available to third parties, including researchers, under certain conditions. A platform may make the data available via an application programming interface (API), as with X or, in some cases, a third party may gather the information themselves by 'web scraping'. If using a third party tool to access social media data, the researcher should also ensure that the tool is compliant with the Terms and Conditions of the social media platform.

NB. When using any third party tool to collect, manage or store personal data, then due diligence must be undertaken on the supplier and appropriate contracts must be in place. A careful and thorough assessment of the security of the tool must be undertaken. It is recommended that researchers contact the IT Services Business Relationship Manager for their faculty for advice *(Note: the assessment process takes 2-4 weeks).*

Other legal considerations include those related to: 1) Data Protection (i.e. if you are storing and processing potentially identifiable social media data);

Social Media and the law (NB. Other laws may apply to research undertaken outside the)

Identifiable and potentially identifiable social media data is subject to regulations set out in the GDPR, and an appropriate legal basis for the processing of personal data must be identified social media data is still potentially identifiable even if usernames have been removed.

Information Commissioner's Office (regulators of Data Protection in UK)

"There are many examples of big data analytics that do involve processing personal data, from **sources such as social media**….where personal data is being used, organisations must ensure they are complying with their obligations.

If personal data is fully anonymised, it is no longer personal data. In this context, **anonymised means that it is not possible to identify an individual from the data itself or from that data in combination with other data, taking account of all the means that are reasonably likely to be used to identify them**...The issue is not about eliminating the risk of re-identification altogether, but whether it can be mitigated so it is no longer significant...**Organisations using anonymised data need to be able demonstrate that they have carried out this robust assessment of the risk of re-identification**, and have adopted solutions proportionate to the risk."(ICO, 2014)

2) Intellectual Property (i.e. copyright on posts and images you may wish to reproduce).

It is the researcher's responsibility to check details of copyright on any material that they wish to make use of from online sources, whether the copyright relates to the organisation hosting the site, or to the individuals using the site.

3. IS IT HIGH QUALITY RESEARCH?

There are many tools available that allow for social media data to be quickly analysed and reported, without much consideration of research methods or integrity. Like all research conducted by staff and students of the University, social media research must meet the standards of research quality and integrity expected by the University (as set out in the Good Research & Innovation Practices Policy) and as appropriate to the discipline of the researcher.

Researchers are also advised to consider the methodological and ethical implications of using platforms and tools that do not enable the researcher's full understanding of the methods used to collect, analyse and report that data.

Whilst this policy note only applies to the use of social media for research purposes, some of the issues discussed may also be appropriate to consider for other uses of social media data (e.g. marketing, public engagement etc) that would not be considered research.

4. ARE THE SOCIAL MEDIA POSTS PUBLIC OR PRIVATE?

A significant area of debate relates to whether social media posts should be classified as public or private.

Whether posts are perceived to be public or private impacts upon whether informed consent should be sought from social media users, however it has no impact upon whether ethical approval should be sought.

All research involving social media data must approved prior to data being collected and analysed.

The British Psychological Society (2013) suggest that whether a post should be treated as public or private largely depends upon the specific online context, and – importantly – it is **the likely perception of the social media user** that is paramount.

Examples:

- Users of a 'private' Facebook group might reasonably expect that their posts are only visible to a restricted number of people and are therefore not 'public'. Therefore, for a researcher to enter the group with the intention of conducting research without the knowledge or consent of moderators and/or users would be deception;
- X users using a #hashtag to make their posts more visible are more likely to consider their posts 'public';
- Users of a public discussion forum on a topic with limited general interest may reasonably expect that only a small number of people are likely to view the posts – they therefore may not perceive them as public.

When assessing the public/private nature of online spaces it's important to take into account that people's perceptions vary, and that not all social media users have a good understanding of how accessible their content is to others. Additionally, a post that a user perceived as private at the

time of posting might become public at a later date (or vice versa). This may arise when privacy settings are changed, or when a post a user thinks that they have deleted is actually retained somewhere (e.g. in a public archive).

5. WHAT IS THE POTENTIAL FOR HARM AS A RESULT OF THE RESEARCH?

As with all research, the potential vulnerability of participants and the sensitivity of the topic needs to be considered (see section 3.1.4 of the Ethics Review Procedure section of the Policy for potentially high risk topics and groups). Researchers should also consider and implement the Preventing Harm in Research and Innovation (Safeguarding) Policy.

Researchers using social media data are at a disadvantage in that they have no direct contact with participants. It is therefore difficult to assess the potential vulnerability of participants. If you suspect that data originates from a potentially vulnerable user, including under 18s, then the data should be removed from the dataset or appropriate measures should be put in place to gain appropriate informed consent for use of the data, including parental consent where appropriate (see Research Ethics Policy Note no.2: Principles of Consent). If engaging with participants online, where it may be difficult to establish the age of the participant, steps may be taken to verify the participants' age, and researchers must carefully consider the legal and ethical dimensions of involving participants under the age of 18.

Research involving sensitive topics, or topics with an increased likelihood of harvesting sensitive data, has a higher risk of causing harm to the social media users, people depicted in social media posts (e.g. people who are named, appear in photos etc), researchers and/or third parties. See section 3.1.4 of the Ethics Review Procedure section of the Policy for information about what classifies as a potentially sensitive topic. It should be noted that under the UK GDPR certain types of sensitive personal data are classified as 'special categories' of personal data and specific requirements apply when processing them; refer to the Specialist Research Ethics Guidance Paper on 'Anonymity, Confidentiality and Data Protection' for more details.

Inflammatory and offensive content is not uncommon on social media, and comments made in the heat of the moment may cause significant harm if they re-surface or are drawn attention to: researchers should be mindful of this when analysing and reporting such data.

The potential of social media research to draw attention to posts and/or individuals that may otherwise have been 'lost in a crowd' should be considered in relation to how such attention may risk causing harm.

As with all research, the sensitivity of the topic impacts upon ethical decision making, but in projects involving social media, special attention should be paid to how users interact with these platforms, how this may be different from interaction in a research setting or face to face, and what the implications are for conducting ethical research. For example, researchers should be aware that participants may consider their social media activity to be private even when they have agreed to the platform's terms and conditions for making their posts publicly available. This may increase the potential for harm should the user later become aware that their data has been used for research purposes, and/or if information about them is published which they never expected to be made public.

The timing of the research is also an issue to be considered in terms of the potential harm to participants. Researching 'live', current social media activity is likely to have a greater potential for harm; for example, due to a greater likelihood of individuals being identifiable, and a greater

risk of altering the behaviour of the participants such as discouraging or changing their use of a particular social media platform. If a researcher intends to analyse current social media activity, then their ethics application should address these issues thoroughly, including consideration of why it is necessary to research current, rather than inactive, discussions.

Some types of social media research involve collecting 'live' social media data as it is generated by users in response to particular types of events (e.g. natural disasters or political events), the specific details of which are unlikely to be known at the time of the ethics application. Due to the need to react quickly to live events, it may not be possible for the ethics application to be specific about the particular activity, but it should nonetheless indicate the type of events that the researcher intends to research, and consider the type of data that may be used, issues of anonymisation, consent, risk and sensitivity, the type of analysis to be conducted, and when/how findings are to be published (i.e. immediate publication online; later publication in an academic journal).

The higher the risk of potential harm the research poses, the more complex it becomes to address issues of appropriate consent and anonymisation, and the increased obligation there is for the researcher to address these issues thoroughly.

6. IS INFORMED CONSENT REQUIRED?

For researchers intending to recruit social media users via a social media platform the informed consent of the participants should normally be obtained in line with Research Ethics Policy Note no.2 (Principles of Consent). Researchers should also seek the permission of the appropriate gatekeeper (e.g. group administrator or forum moderator) when seeking to engage with members of an online community. For research involving social media data, an assessment of the public/private nature of the post will impact upon whether informed consent should be sought and, if so, who from. As stated by the British Psychological Society (2013):

> "Where it is reasonable to argue that there is likely no perception and/or expectation of privacy (or where scientific/social value and/or research validity considerations are deemed to justify undisclosed observation), use of research data without gaining valid consent may be justifiable."

Whether informed consent is needed or not does not impact upon the need to get ethical approval. The ethics application should explain decision making with respect to whether or not to gain informed consent.

Observation of online public spaces

As with all research involving observation of public spaces it is recognised that it is often infeasible and unnecessary to gain the consent of all that may be observed. However, as stated in Research Ethics Policy Note no. 2 (Principles of Consent), if researchers are observing individuals in public places then unless consent is gained, "specific individuals should not be identified, explicitly or by implication, in any reporting of the research, other than public figures acting in their public capacity (as in reporting a speech by a named individual, for example)". In such cases, if appropriate anonymisation is used (see section 7 below) then it may be appropriate to argue that consent is not required.

Observation of online spaces that may be perceived as not fully public by social media users

In cases where social media users may perceive their posts as not being fully public, it may be necessary to gain appropriate consent. What is appropriate will depend on the nature of the research in question. For example, if the social media data is likely to be perceived by users as fairly public, the research is low risk, and the analysis is at the population level and no users will be identified, then it may be appropriate to check that the terms and conditions of the platform state that the users have explicitly agreed to allow their data to be used for research and/or to get consent from a gatekeeper (e.g. forum moderator, group administrator).

However, the less public the data, the higher risk the research and/or the more individual the analysis becomes, the more it will be necessary to consider how to gain informed consent from gatekeepers and/or individual social media users for:

1. Data harvesting and/or analysis;
2. Quoting or reproducing social media posts;
3. Identification of social media users in publications and tools.

Depending upon the nature of the research it may be appropriate to get consent from gatekeepers and/or individual social media users for some or all of the above.

In making a decision about whether and how to gain informed consent the following should be considered:

- Explicit statements on the website or in the terms and conditions of the platform
- The perspective of gatekeepers (e.g. forum moderators, group administrators) regarding the users' preferences about the use of their data
- The potential harm to the community if they become aware of a researcher observing their interactions (see British Psychological Society (2021) Principle 3: Social Responsibility p. 7)
- Whether the nature of the research means that it is appropriate to covertly observe a non-public space (see Policy Note no. 2 (Principles of Consent) with respect to research involving principled deception (section 6))
- How practical it is to gain consent from the appropriate people (e.g. could individuals be directed to a website that contains information about the research? Can consent be gained directly within the platform e.g. via a direct message?)
- Should participants be offered the opportunity to consent (or not) to different things e.g.
    - Having their interactions observed;
    - Being identified in reports and publications;
    - Being directly quoted;
    - Having posts reproduced in publications.

Deleted posts

A significant issue arising in social media research is how to handle deleted posts. If the researcher collects their data before the post is deleted, then the researcher may be unaware of the deletion and analyse it alongside other still existing data.

If a user deletes a comment this suggests that they do not want others to see it, and this might be interpreted as equivalent to a request to withdraw consent for use of data (whether or not direct consent was obtained). It is therefore important to ensure that ethical decision making around reporting social media data takes into account such an eventuality whilst maintaining the integrity of the research, and that researchers consider what they will do if they become aware that there are deleted posts in their dataset.

Research by IPSOS MORI (2015) suggests that the public in general are uncomfortable with researchers' use of social media data.

Only 38% of respondents were aware that social media companies share individuals' social media data with third parties, such as the government or companies, for research purposes - and 60% of respondents believed this should not be happening.

Whilst the public were more favourable towards university researchers analysing social media data (more so than researchers based in government departments and companies), rates of acceptance were still low (approx. one third). Out of a number of scenarios presented to respondents, the one rated most favourably in terms of ethicality was still only deemed ethically acceptable by 50%. This scenario involved the following conditions being met:

-The researchers were based in a University or similar organisation
-They were only using the data of social media users who had **opted in to their data being used for this specific project**
-They were collecting data related to use of a specific word, hashtag or phrase relevant to the project
-The researchers were aiming to review or act on **comments about a product or service they deliver.**
(IPSOS MORI, 2015)

These findings suggest a lack of awareness and consent for academic use of social media data for research purposes, and challenge assumptions of implied informed consent to conduct research using social media data.

Whilst these findings should not necessarily stop social media research being conducted, they do suggest that issues of consent need to be thoroughly considered, and that ethical practice may also involve more open and public discussion about social media research methods, and the contribution that such research makes to society.

7. CONFIDENTIALITY AND ANONYMISATION

Unless a researcher seeks explicit consent from a social media user to identify them in the research, **appropriate steps should be taken to anonymise individuals in publications and other outputs, unless the individual is a public figure acting in a public capacity** (see Research Ethics Policy Note no.2 (Principles of Consent)). This is the case whether the social media data is perceived to be public or private. The need to anonymise applies both to individual social media users, and to other individuals that they mention or depict in their posts.

In the case of photographs of people which have been shared on social media, the researcher should consider whether the person depicted has consented to their photograph being taken and shared. For example, for a stock image of a model, we can assume that consent has been gained from the model for taking and reproducing the image – although the researcher may need to check whether the image is protected by copyright. On the other hand, in the case of a photograph of an individual taking part, for example, in a protest, we cannot assume that the individual has

consented to the image being taken and shared; furthermore, its reproduction could cause harm to the individual.

How to anonymise social media data

- The researcher should only collect information that they need to do the research (is the collection of usernames, profile descriptions, profile photos, date of birth, location etc. really necessary?).
- The researcher should consider replacing information that could be used to identify individuals (e.g. usernames) at the earliest opportunity. Remember that such datasets are often re-identifiable, so they should still be treated as though they were identifiable data, and should be treated in line with data protection legislation. If potentially identifying information (e.g. usernames, locations) needs to be retained in order to conduct the analysis then, unless the researcher has gained consent to identify users in reports, in most cases users should be anonymised in the reporting of research (e.g. by using pseudonyms and image editing software such as Adobe Photoshop to hide identifying information and images in screenshots).
- Beyond using pseudonyms and removing identifying information, it is also recommended that, if the researcher wants to report direct quotations, then they should paraphrase the quotation in a way that means it cannot be used to locate the quote online (e.g. through a search engine) but still retains the original meaning. For higher risk research this should be standard practice. Advice on anonymization practices can be found here (British Psychological Society, 2021 p. 18; Townsend and Wallace, 2016, pp. 11-12). Paraphrasing is used because it is fairly easy to trace the source of direct quotations using a search engine.

Anonymization practices sometimes go against the Terms and Conditions of some platforms (e.g. X states that post must be given in their original form and attributed to the individual who made the post). In such cases careful consideration needs to be given as to what is ethically appropriate as well as what is in accordance with the Terms and Conditions of the Social Media platform

8. DATA STORAGE, SHARING AND RE-USE

As with all research, consideration needs to be given to how data obtained from social media will be stored, shared and archived. As discussed above, potentially identifiable data is regulated under the UK GDPR, and researchers are advised to follow University of Sheffield Research Data Management guidelines in relation to handling such data. The terms and conditions of the relevant social media platform and, if relevant, commercial data provider, should also be checked for requirements relating to data storage, sharing and archiving. In the case of contradictory demands, advice can be sought from UREC.

Some providers of social media data allow researchers to analyse data online, rather than needing to download and store it themselves. If these tools are provided legally and in line with the terms and conditions of the social media platform, then they may be a suitable alternative to downloading and storing data. However, such tools are not always transparent about how data are collected, analysed and presented, which can raise separate research integrity and ethical issues as discussed in section 3 above.

References

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The University of Sheffield
Research Ethics Policy Note no. 15

DEMONSTRATING THE IMPACT OF RESEARCH AND OTHER FORMAL UNIVERSITY EVALUATION EXERCISES

Researchers are increasingly required to demonstrate the impact of their research to funders, and as part of the UK Research Excellence Framework or similar research evaluation exercises. The University is also frequently required to undertake data collection exercises to formally evaluate activities in a range of other areas (e.g. teaching, student access and participation), and to provide reports to regulatory bodies such as the Office for Students or as part of recognised external frameworks such as the Athena Swan Charter.

In collecting evidence to demonstrate impact or to formally evaluate an activity as set out above, researchers need to consider whether this data collection in itself constitutes a form of research which requires ethics approval according to the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue.

The definition of research is set out in the General Principles and Statements section of the Ethics Policy. Evidence to demonstrate impact or evaluate an activity may be obtained in a variety of ways, and may involve seeking the opinions or recommendations of relevant individuals (e.g. those who have attended public engagement events; employees of organisations who have drawn on the outputs of a research project to enact a change in their organisation; students who have participated in access and participation events).

Ethics approval will NOT be required where:

- data is collected from human participants with the intention of using it specifically and solely for the purposes of evaluating the impact of a research project OR for formally evaluating an activity undertaken by the University to meet the requirements of regulatory bodies or recognised external frameworks; AND
- personal data* will only be used by members of the research/evaluation team and, if required, an evaluation panel for assessment and reporting as part of a formal evaluation process (e.g. as part of the UK Research Excellence Framework, Teaching Excellence Framework, Access and Participation Plans, or similar).

However, ethics approval should be obtained BEFORE the collection of data commences in the following cases:

(1) Where data collected from human participants will also be used for further analysis for the purposes of generating new knowledge and understanding as part of a research project or in fulfilment of a student research assignment.
And/or
(2) Where data collected from human participants will be made accessible to an audience beyond the research/evaluation team (other than as part of a formal evaluation process e.g. routine data collection and evaluation, and publication/sharing of evaluation findings, as required by the Office for Students). This includes publication though informal channels such as blog posts, as well as more formal research outputs such as academic papers and conference presentations.

Even if formal ethics approval is not required as in the cases mentioned above, care needs to be taken to ensure that people involved in activities exempt from research ethics approval are treated ethically, i.e., that potential risks to their dignity, rights, safety and well-being are managed and mitigated. Similar consideration should be given to managing and mitigating any risks to external organisations through their involvement in evaluation activities.

Those involved in collecting data for these purposes should consult the University's research ethics and safeguarding in research policies and guidance for information about how to approach this. In addition, TASO (Transforming Access in Student Outcomes in Higher Education) provides guidance and resources to support ethical data collection for evaluation activities relating to student access and participation.

There may be circumstances in which data collected for the purposes of the evaluation activities described above may become of research interest. Information about the ethics requirements for the re-use of existing data in research can be found in Research Ethics Policy Note no. 13.

*The UK data protection legislation must be complied with in handling personal data from a living individual. For example, where identifiable quotes or other personal data from named individual(s) is to be included in information that is to be provided to an external party such as a formal evaluation panel (e.g. as part of a REF Impact Case Study, which may also be made publicly available), then explicit informed consent for this must be obtained for the relevant individual beforehand, unless the data is already in the public domain.