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 mission is to uphold the ideals of discovery, to encourage and support research into new ways of acquiring, investigating and developing knowledge for the good of society, and to ensure that all research is conducted in accordance with ethical principles.

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: personal information or identifiable data should not be disclosed without participants' consent;
- security of their data: data and samples collected should be kept secure and anonymised where appropriate;
- safety: participants should not be exposed to unnecessary or disproportionate levels of risk, and;
- request erasure of their data 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 possible 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. An ethical approach to research involves, rather, 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 INTRODUCING RESEARCH ETHICS

The University's definition of research is taken from the Research Excellence Framework 2014: **'a process of investigation leading to new insights, effectively shared'**. This applies to all research undertaken by, or on behalf of, the University, across the full range of academic disciplines, from the arts and humanities to the natural sciences (whether funded or not), and also encompassing administrative research (undertaken within, or on behalf of, professional services departments or academic faculties/departments), and research undertaken by or within University research centres/institutes, advisory/consultancy services and subsidiary companies. This definition includes:

- work of educational value designed to improve understanding of the research process;
- work of relevance to commerce and industry;
- work of relevance to the public and voluntary sectors;
- scholarship supporting the intellectual infrastructure of subjects and disciplines (such as dictionaries, scholarly editions, catalogues, and contributions to research databases);
- the invention, design and generation of ideas, images, performances and artefacts, where these lead to new or substantially improved understanding; and
- the experimental use of existing knowledge to develop, design and construct new or substantially improved materials, devices, products and processes.

This definition of research excludes:

- the routine testing and analysis of materials, components and processes - e.g. for the maintenance of national standards - as distinct from the development of new analytical techniques;
- routine audit and evaluation, within the established management procedures of organisations; and
- the development of teaching materials that do not embody original research.

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 these terms 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.

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 be an unrealisable goal. 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.

This means that the formal ethical review of research proposals involving human participants, personal data or human tissue is best carried out within departments, within the broad parameters provided by this Policy and the Research Ethics Approval Procedure.

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 departmental researchers 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 personal data. As in all other matters, individual researchers are expected to follow the leadership of their Head of Department.

In everyday research practice, however, the first responsibility for considering, respecting and safeguarding the dignity, rights, safety and well-being of human participants involved in 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. These are:

- the human participants involved (as defined by this Policy);
- 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 it 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 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, 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.

This specifically 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'.

The University of Sheffield's Policy is designed to complement the National Health Service (NHS) ethics review system. The University's Ethics Review Procedure 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. External bodies that have professional licensing or registration responsibilities are, however, a different matter and their external principles have a different weight. 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, from senior management policy-making to the practicalities of individual staff and student research projects;
- 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; 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 it 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, as well as they can, from avoidable harm arising from their research. Researchers also have a responsibility to consider their own safety and that of any co-researchers or collaborators.

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 in prospective participants' future lives as a result of 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.

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 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.

This approach applies to all University 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 ensure that ethics approval for their research project(s) is obtained via an appropriate route (e.g. via the ethical review procedure at their own University or organisation).

The University's definition of research is 'a process of investigation leading to new insights, effectively shared'; the full details are outlined in the General Principles and Statements section of this Policy. The definition of a 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 Research Ethics Policy Note no. 3.

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 five 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 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.

In addition, 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. Appropriate Bodies include some NHS research ethics committees and the Social Care Research Ethics Committee (see section 2.3). 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'.

2.1 The University Ethics Review Procedure (University Procedure)

This applies to research which:

- comes under the broad definition of 'a process of investigation leading to new insights, effectively shared';
- is led by the University of Sheffield;
- does not require ethical review via an NHS Research Ethics Committee or the Social Care Research Ethics Committee; and
- is undertaken in the United Kingdom (or abroad, unless there is an appropriate alternative – see section 2.4 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 Heath Research Authority's HRA Approval process. In general, review by an NHS REC will be required for research that involves participants identified from, or because of, their status as patients of the NHS or other Department of Health Services, and/or the relatives of such patients. 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 the collection of human tissue). Research involving only the premises and/or staff of the NHS or other Department of Health 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 national Social Care Research Ethics Committee

This route applies to certain types of social care research. For guidance refer to: http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/ and Research Ethics Policy Note no. 5.

2.4 The Alternative Ethics Review Procedure

This applies to:

- research led by University of Sheffield staff or students which is conducted outside the United Kingdom; or
- research in which University of Sheffield staff or students may be involved, but which is led by another United Kingdom university or research organisation (which may be conducted either within or outside the United Kingdom).

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

2.5 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 3.1.8 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, with the exception of Student Services which has a tailored paper-based process with additional steps incorporated (NB. specific details relating to administrative research are provided in Research Ethics Policy Note no. 7). 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 3.1.8 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 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 a designated Ethics Administrator who is 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 the key resources for ethics reviewers provided on the central ethics web pages, including the slides delivered at ethics reviewer workshops, and the quick reference guide for reviewers, available here: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/further-guidance/universityprocedure2/reviewersc;
- read one or more of the training examples of ethics applications with reviewer comments, available here (in the section headed 'Case Studies'): https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/educationresources/trainingresources;
- 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 at: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/index

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 University Research Ethics Committee (see section 3.1.5 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 University Research Ethics Committee for advice on how to seek ethical approval.

3.1.2 How is a research project submitted for ethical review?

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: https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/educationresources/onlinesystem

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. 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.

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.

3.1.3 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:

3.1.3.1 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 3.1.5).

3.1.3.2 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 tickbox 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.

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 Ethics Administrator and 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 five years, i.e. a new generic ethics application should be submitted for review.

3.1.4 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 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.

3.1.5 How is the ethical review of a project carried out?

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, 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 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 supervisor or reviewer concerned, at which point the decision may be amended. If the Ethics Administrator 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, application. None of the ethics reviewers may have any conflict of interest with the application.
- 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 not have any 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 3.1.3.2.
- 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 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 Minute 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 sub-committee of the University Research Ethics Committee, comprising two ethics reviewers from the project's department of origin, one external 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. In such cases, the departmental Ethics Administrator should liaise with the UREC's Minute Secretary to identify appropriate ethics reviewers from the UREC.

3.1.6 What are the possible outcomes of the ethical review of a project?

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):

- *Approval*: the project can go ahead with no changes.
- *Approval with suggested amendments*: the project can go ahead but the applicant may wish to consider suggestions made by the reviewer(s); these, however, are optional.
- *Approval with compulsory changes*: the project cannot go ahead until required changes have been made; the reviewer(s) must see the revised version of the application and subsequently approve it. (Suggested amendments can also be made alongside the compulsory changes)
- *Rejection (not approved)*: 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, 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.

Ethics reviewers have, with the applicant(s), responsibility for the quality of the ethics application. Where they 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.

3.1.7 How long will it take to obtain ethics approval for a project?

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, if an application is judged contentious, or if the applicant appeals against the ethics decision.

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). 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.

3.1.8 What happens if changes are made to the project after ethics approval has been obtained?

In this situation, the researcher must consider whether the proposed amendment constitutes a significant change that could have a potential impact on the dignity, rights, safety and well-being of the participants. A 'significant change' refers to a new research approach or method that, had it been planned at the time, would have been mentioned on the original research ethics approval application. Examples of this include:

- 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; or
- a different venue for data collection.

This list is indicative, rather than exhaustive. In such cases, or if there is any other doubt about whether a proposed change is significant, the researcher should contact the departmental Ethics Administrator who will then provide the details to one of the ethics reviewers who originally reviewed the project (ideally the lead reviewer, where relevant). The reviewer should then consider the changes and liaise with the Ethics Administrator to advise the researcher on the appropriate course of action. This could involve re-applying for full ethics approval, if the changes are particularly significant; alternatively, the reviewer may be happy to approve the changes immediately (it is left to the discretion of academic departments to decide departmental procedure in this regard). The Ethics Administrator should make a record of the proposed changes and the actions that were undertaken as a result, and upload a copy of this to the original approved application in the online Ethics Application System.

The requirements of this section do not apply to the routine, everyday adjustments to data gathering plans and activities that researchers must often make in response to the contingencies of research. Nor does it apply to minor corrections in the written information given to participants, such as remedying spelling errors or typos. Discretion, responsibility and common sense are necessary in interpreting this section: researchers are required to reflect upon what they are doing, its relationship to their original ethics approval application, and whether any ongoing adjustments are significant, in the terms outlined above.

3.1.9 Retrospective Ethics Review

Research involving human participants, human tissue or personal data should not begin before research ethics review has taken place 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, 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.

3.1.10 When is research ethics approval NOT required?

Ethics approval is not required in the following situations:

- 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) 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.

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).

3.1.11 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 Policy Governing Research Involving Human Participants, Personal Data and Human Tissue

Should, for whatever reasons, concerns arise about whether a research proposal or ongoing research activity complies with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, the Chair of the UREC should contact the Head of the Department concerned, as the person ultimately responsible for the implementation and observance of the Policy within that Department, requesting that the research activity in question, or the approval process with respect to the proposal in question, 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. 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 3.1.12 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 and the issue should be investigated informally. If the concerns are substantiated, the Chair of the University Research Ethics Committee should be informed and the University's Policy on Investigating and Responding to Allegations of Research Misconduct, or another appropriate University procedure, may be activated (further details are set out in the University's Good Research & Innovation Practices policy).

3.1.12 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 Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, 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."

Such breaches are extremely rare. 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 or PhD upgrade process 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 in line with the principles of natural justice and 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 though that all researchers are expected to be familiar with the ethics review procedure and 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 halted with immediate effect on the instruction of the Head of Department;
ii. The Head of Department informs the UREC and the Student Conduct & Appeals Office 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 should be informed of the department's concerns as soon as possible. They should be given at least three days' notice of any investigative meeting 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 and the Student Conduct & Appeals Office, along 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, plus the relevant faculty representative, considers the report and provides appropriate advice and support;
vi. The UREC and the department agree on the final outcome of the incident and any action that needs to be taken (for example by considering any implications for the assessment criteria);
vii. The investigation, review and agreement on action all take place in a timely manner, as agreed by the Head of Department, the UREC and the Student Conduct & Appeals Office.

4 THE ALTERNATIVE ETHICS REVIEW PROCEDURE

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 is subject to a robust ethics review process prior to the involvement of the human participants.

4.1 Research conducted overseas

Research that will take place in another country and will involve human participants from that country may require ethics approval via an appropriate ethics review procedure in that country. A review and assessment of how local approval is obtained is an essential part of the ethical review process. Where such a 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 overseas procedure is judged to be sufficiently robust by the UREC (refer to Section 4.2.1 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).

4.2 Research led by another United Kingdom university

If the University is collaborating with another United Kingdom university and the other United Kingdom university is the lead partner, then the ethics review procedure in place within the other United Kingdom university should apply, rather than the University of Sheffield's Procedure. However, as with research conducted overseas, this is subject to the condition that the other United Kingdom university's ethics review procedure is sufficiently robust (see Section 4.2.1 for details).

4.2.1 Judging the robustness of another institution's ethics review procedure

A list of institutions with ethics review procedures that have already been judged to be sufficiently robust is provided at:
https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/alternative

Where ethics approval will be sought via the ethics review procedure of one of the institutions listed, no further information will be required about the robustness of the procedure. However, following the ethics decision, the researcher must create a new ethics application in the online Ethics Application System, selecting the option that confirms that the research is either taking place outside the UK, or is being led by another UK institution, and then follow the process for submitting copies of (1) the research ethics application form and (2) a letter from the institution's ethics body confirming its ethics decision with respect to the project.

Where ethics approval will be sought via the ethics review procedure of an institution that has not already been judged to be sufficiently robust, the researcher must provide the following information to the UREC's Minute Secretary:

- A copy, preferably electronic, of the institution's research ethics application form, in order that this can 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 the same criteria.
- Information on the ethics reviewers, if known; in particular, the number of ethics reviewers and details of their employers. If the institution's ethics review procedure has a website in English then the details should be provided.

The UREC's Minute Secretary will review the information provided within a short period of time and confirm whether or not the institution's ethics review procedure is deemed to be sufficiently robust.

If the procedure is deemed to be sufficiently robust, the researcher should then submit the project for ethical review via the approved procedure in the other institution. Following the ethics decision, the researcher must create a new ethics application in the online Ethics Application System, selecting the option that confirms that the research is either taking place outside the UK, or is being led by another UK institution, and then follow the process for submitting copies of (1) the research ethics application form and (2) a letter from the institution's ethics body confirming its ethics decision with respect to the project.

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.

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, or observational research), 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.).

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.

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 Good Research & Innovation Practices 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 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’

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 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;
- processing of genetic data or biometric data for the purpose of uniquely identifying a natural person;
- criminal records or allegations

Data that falls 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* (HTA Act) as *relevant material* (the HTA website: www.hta.gov.uk). The relevant materials covered by the HTA Act 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). Cell lines which are intended for human application (i.e. for clinical uses or treatment) are considered relevant material under the European Union Tissue and Cells Directive (Directive 2004/23/EC). Storage of cell lines for research-only purposes does not require a licence; storage of cell lines for potential human application does. The HTA Act does not cover hair and nails from a living person. However, the HTA Act makes it a criminal offence to hold relevant material – including hair, nail, and gametes (i.e. cells connected with sexual reproduction) – for the purpose of DNA analysis, without the informed consent of the person from whom the relevant material came (or of those close to them if they are deceased).

For further discussion of the legal 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'.

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 people* in order to **collect individuals' 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'

* 'people' 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.

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 people 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 people, whatever their role or status, for the purposes of analysing their opinions as research data, will require ethics approval.

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

A co-production research project in which the members of a community group will work with the academic researchers to collect and analyse research data from the wider community, including providing their own opinions as research data.	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, 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.

Examples of when ethics approval is NOT required:

In general terms, ethics approval is NOT required where a project will involve interaction with people* **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).

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	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

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.	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.
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.

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

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 EU, 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 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. 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 her/his 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 be obtained in writing. This is the 'gold standard' of informed consent.

Where this is not possible, documented oral consent is an acceptable alternative. Ideally oral consent should either be tape-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.

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 s/he 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 her/his 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'.

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.

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 help her/him 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 consent is not being used as the legal basis for the use of the child's personal data, 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. Ideally, explicit, opt-in informed consent processes should be used, unless there is an alternative legal basis for the processing of personal data (for example, where processing is necessary 'for the performance of a task carried out in the public interest').

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 three, equally important, special responsibilities under this Policy:

- to ensure that there is an appropriate alternative legal basis for the processing of the participants' personal data (since this cannot be achieved via consent) – see section 2 of this Policy Note for more details);
- 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 five, equally weighty, special responsibilities under this Policy:

- to ensure that there is an appropriate alternative legal basis for the processing of the participants' personal data (since this cannot be achieved via consent) – see section 2 of this Policy Note for more details);
- 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 her/himself is unsure of her/his role, particularly with respect to when s/he is '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/for-organisations/education/.

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 generic 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.

Researchers should ensure that they are aware of the potential risks to the safety and well-being of participants, and should consider carefully how these risks can be managed; such considerations should be set out fully as part of their ethics application. Potential risks to participants' safety and well-being should be discussed openly 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 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, who will be able to escalate their concern, within a reasonable time period, if, following participation, they experience stress, harm or have any other concerns about the research.

If during research a researcher obtains evidence of physical or psychological problems the researcher has a responsibility to inform the participant if s/he believes that by not doing so the participant's future well-being may be compromised or diminished. If the issue is serious and 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 (i.e. trial subjects and/or patients) are deemed likely to be outweighed by the potential benefits for them and for future patients. In certain cases a patient may explicitly support a research project and support invasive treatment that may be very harmful if, due to the particular circumstances (for example, if s/he is terminally ill), s/he feels that it is worth taking a significant, potentially life- threatening risk. This example represents the point at which participants may feel 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 (for example 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 judgment 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 Ethics Administrator.

Researchers should give appropriate consideration to the potential risks to themselves and to others who may be involved with, or affected by, the research. Appropriate steps should be undertaken to mitigate these risks (e.g. undergoing a risk assessment process, implementing a lone work policy – further guidance may be found on the University's Health and Safety webpages, and departments may have their own policies and procedures in place).

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. 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 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, 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 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 who 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).

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 always think carefully about (a) whether it is necessary to use identifiable personal information, (b) what is the earliest stage at which de-identification might be possible without compromising the integrity of the research and (c) how full, robust anonymisation can 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 the vast majority of research undertaken at the University, this will bethat '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 'consent' is not being used as the legal basis for processing personal data, it may be possible to use personal data without consent - when the material is already in the public domain, for example. However, from an ethical perspective, consent is still to be preferred, unless it can be shown to be inappropriate for some reason. If a researcher intends to process data without consent, then further advice should be sought.

When gathering identifiable personal information researchers should aim at all times to 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 the uses to which data will be put and any risks that might be involved. Further information can be found in Research Ethics Policy Note no. 2 'Principles of Consent'.

Personal information must be kept secure at all times. The level of security should be proportionate to the risks inherent in the nature of the data, but all personal information should be kept securely e.g. portable devices should be encrypted. 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. The participant 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 the participant 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.

Finally, 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. Any use of such confidential information that exceeds that which an ordinary person could reasonably be said to expect constitutes a breach of confidence.

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'.

NB. The University has a separate policy covering the transfer of research data which relates to human participants between Principal Investigators within the University of Sheffield.

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), and the procedure established by the national Social Care Research Ethics Committee. The University's Ethics Review Procedure does not duplicate the functions, or overlap with the remit, of the NHS ethics review system or the national Social Care Research Ethics Committee.

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. 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, 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 include certain NHS Research Ethics Committees and the 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 or refine relevant questions with scientifically sound methods'.

Thus 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, may still require ethical review via the University's Ethics Review Procedure (e.g. studies classed as service evaluation by the HRA, but which are undertaken by a student as the research element of a University degree award).

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 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 'research that involves human participants who have been identified through the social care services of Sheffield City Council with the aid of Council resources'.

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

Health care research is reviewed 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 from, or because of, their status as patients of the NHS or other health services of the UK Devolved Administrations, and/or the relatives of such patients. 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. 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, and those which involve NHS staff or premises.

3 ETHICS REVIEW PROCEDURE FOR SOCIAL CARE RESEARCH

The national Social Care Research Ethics Committee (SCREC) is part of the HRA. The University's Ethics Review Procedure does not duplicate the functions, or overlap with the remit, of SCREC. SCREC generally expects to review particular categories of social care project, 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; full details can be found on the HRA's website:

http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/.

The SCREC does not review studies involving clinical interventions. Such research should be reviewed by an NHS REC.

If social care research does not require review by an NHS REC or SCREC, 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 departmental Ethics Administrator should be notified of social care research projects, so that they can 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). SCREC as well as NHS REC established in England and Wales are recognised for this purpose. The MCA applies only to people aged 16 and over.

The MCA does not apply to Scotland. In Scotland medical research which involves people aged 16 or over who lack capacity requires approval from an NHS REC. There is currently no equivalent law on mental capacity in Northern Ireland.

For further information, see the Specialist Research Ethics Guidance Paper dealing with 'Research involving adult participants who lack the capacity to consent'.

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 affected by the University's research.

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) and themselves;
- 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 including information sheets.

Among the categories of people who are perceived to be likely to be 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 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:

- '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. 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 perpetually reflective 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 as many choices and options as possible.
- Be aware of the risks to researchers themselves, as well as to participants, 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 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

In 2009, the University's Senate approved a proposal by the University Research Ethics Committee (UREC) that all empirical investigations, other than audits and evaluations, carried out by, or on behalf of, Professional Services departments of the University (i.e. 'administrative research') should be subject, as research, to research ethics review. 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. 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 that should govern the conduct of the research. The University of Sheffield is the contracting body and the University's Policy applies 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 Policy's details.

Such research must be approved in accordance with the University of Sheffield's 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

All archival research that involves 'personal data', whether in public or private archives, requires ethics review and approval via the Research Ethics Approval Procedure. The University's Research Ethics Policy uses the General Data Protection Regulation 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'

Archival research involving personal data is subject to all the strictures and principles of the Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue.

2 OTHER ETHICAL ISSUES IN ARCHIVAL RESEARCH

Notwithstanding the above, much archival research relates to individuals who are not living and, therefore, does not involve 'personal data', thus defined. This does not, however, mean that there are no ethical issues involved in this kind of archival research.

Public 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 private archives (which should be taken to mean everything from modest files of individual or family documents to large, managed documentary repositories, and to include on-line material as well as hard copy).

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).

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 her/himself of the propriety and legality of her/his actions in this respect.

Finally, it should be remembered that the dead may have living relatives, whose sensitivities should at least be explicitly considered. This does not mean that those sensitivities should always be able to prevent research or publication. It does mean that researchers should be clear and transparent about their reasons for setting such sensitivities aside, should they deem this to be necessary or appropriate.

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 three 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

In the United Kingdom, the use of human tissue or primary cells for research purposes is legally regulated; primarily by the Human Tissue Act 2004 (HTA). The Act makes it a criminal offence to engage in various activities involving human tissue and cells, such as storage without a licence (issued by the Human Tissue Authority) or using human tissue or cells outside a research project that has been authorized and approved by a 'recognised ethics review committee' (RERC).

University research ethics committees are not 'recognised' committees for this purpose and researchers will therefore have to seek approval from a RERC prior to commencing research in order to ensure that the research complies with all the ethical and legal requirements. Currently, RERCs are all Research Ethics Committees under the auspices of the National Research Ethics Service (NRES) within the National Research Ethics Service (NRES) for England or within the wider UK Health Departments' (UKHDs) Research Ethics Service, together with all ethics committees recognised by the United Kingdom Ethics Committee Authority (UKECA) under the Medicines for Human Use (Clinical Trials) Regulations 2004.

The types of human tissue and cells that are covered by the HTA are referred to as 'relevant material'. The relevant materials covered by the HTA include materials 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. 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 next paragraph).

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 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 does require institute signature which states they will abide by the "Code of Practice for the Use of Human Stem Cell Lines".

The HTA does not cover hair and nails from a living person. However, the HTA makes it a criminal offence to hold human tissue - including hair, nail, 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 Human Tissue Authority of premises as approved storage facilities for human tissue - for further details of which consult the Specialist Research Ethics Guidance Paper, 'Human tissue research' - and the *ethics approval* of research involving human tissue.

Ethics approval by a RERC for human tissue research is a legal requirement under the HTA in the following circumstances:

- if a specific research project involves the storage or use of relevant material on premises without a licence from the Human Tissue Authority 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 – human tissue or cells – can be obtained for research purposes in two ways:

First, it can be obtained from a human tissue bank that is licensed by the Human Tissue Authority to house tissue for unspecified research. The research purpose(s) must, however, be specified prior to the use of the tissue or cells, and must comply with the human tissue bank's conditions, which will include:

- evidence of independent scientific approval;
- compliance with the terms of the donor's consent;
- anonymisation of the relevant material at the point of release; and
- compliance with a supply agreement.

Second, it can be obtained by application to a RERC for ethics approval for a specific research project that will include the collection of human tissue or cells. At the end of a research project the relevant material must be handled in one of the following three ways: deposited in a human tissue bank licensed by the Human Tissue Authority; used for a new research project (after new RERC ethics approval); or destroyed.

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 her/his research project requires ethical approval from any of the above bodies, or the University's Ethics Review Procedure s/he must seek guidance from UREC.

For further information and discussion, see the Specialist Research Ethics Guidance Paper, 'Human tissue research'.

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.

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 have responsibilities to participants, too, as outlined in this Policy. 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.

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 Ethics Administrator 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.

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, post codes, phone numbers, user IDs, IP addresses etc.). However, consideration should still be given to any new research purpose, in terms of whether the original participants (or relevant groups of individuals) would be likely to object should they become aware of the 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). In such cases, 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 truly anonymised data, although from an ethical stand point, 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, along with 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 the data has been robustly anonymised, then it would be 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. In particular, the 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. 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 directly 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 in to the informed consent process. As such, where a researcher plans to use the data for secondary research (or to share the data) they should include details of this in the information given to potential participants, and include an appropriate section on the consent form.

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 Minute 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 DATA

1. BACKGROUND

Social media are communication tools that allow users to share information and communicate online. The content they create may be publicly available, or access may be restricted to specific individuals or members of a group or community. Examples of social media platforms include Facebook, Twitter, Weibo, blogging sites (e.g. Wordpress), video sites (e.g. Youtube), online 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 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 etc)
- other user data that is collected by the social media company possibly without the user being aware e.g. location data.

Depending upon the nature of the research, social media data 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

In all cases where social media data is being used for research purposes, ethical approval must be gained prior to collecting and analysing data.

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.

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 data. However, a number of organisations and networks have published more general guidelines and frameworks for assessing the ethical issues related to research using social media data which the UREC recommends for further reading. For example:

- AOIR Association of Internet Researchers (2012). Ethical decision-making and Internet research 2.0: Recommendations from the AoIR ethics working committee. Available at: http://aoir.org/reports/ethics2.pdf
- British Psychological Association (2013). Ethics Guidelines for internet-mediated research. Available at: http://www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf

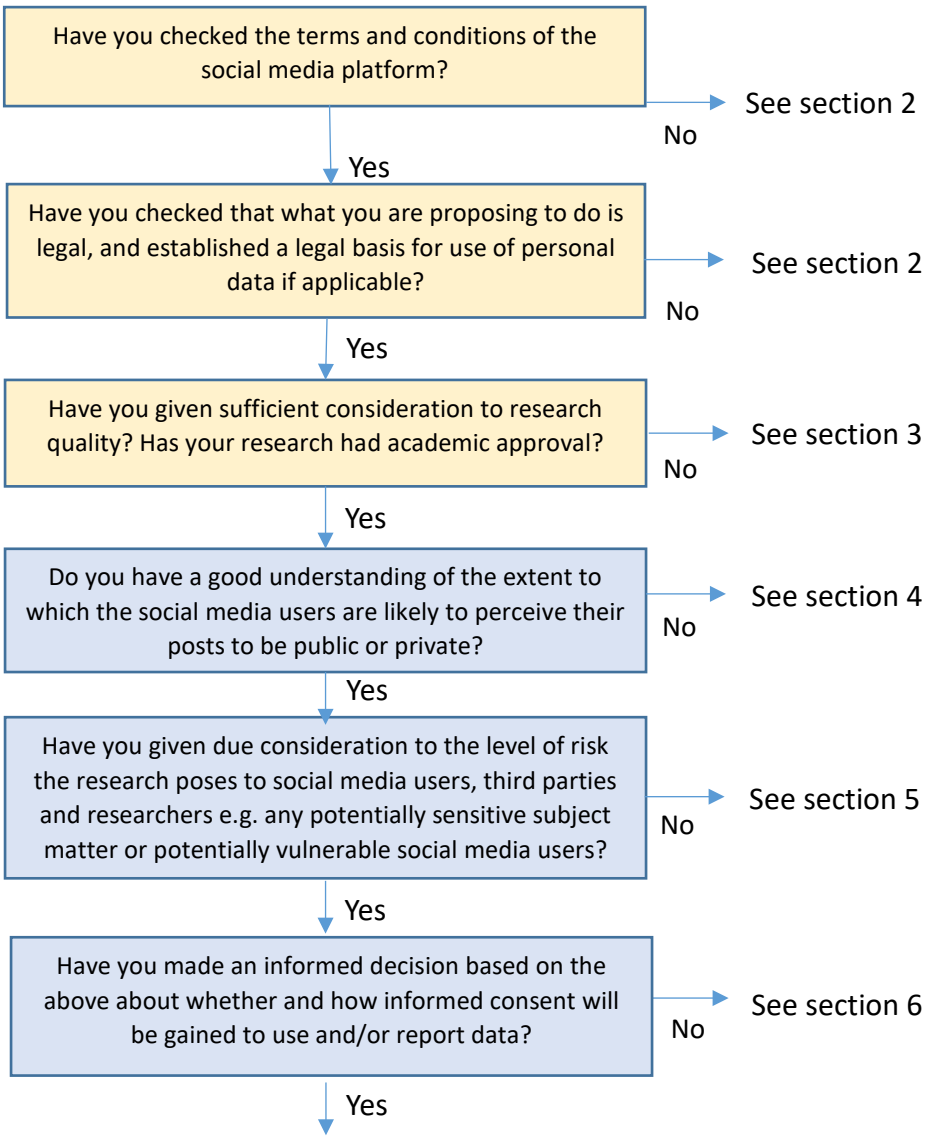
- ESRC (n.d.) Internet-mediated research. Available at: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/frequently-raised-topics/internet-mediated-research/
- Townsend L. and Wallace C. (2016). Social Media Research: a guide to Ethics. Available at: www.dotrural.ac.uk/socialmediaresearchethics.pdf
- Zevenbergen. B et al (2016). Networked Systems Ethics. Available at: http://networkedsystemsethics.net/index.php?title=Networked_Systems_Ethics

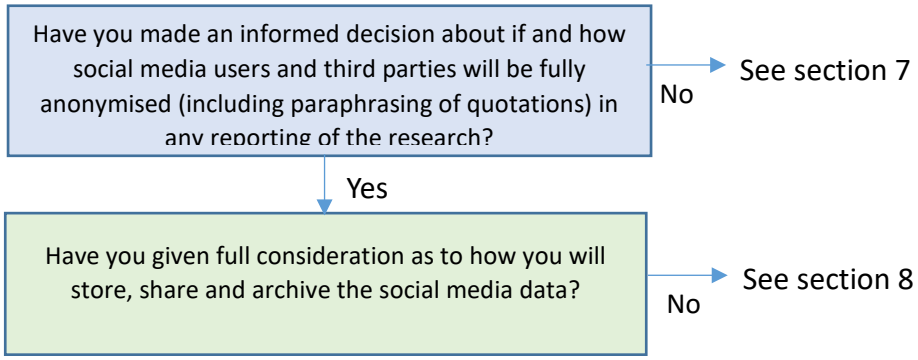
This policy note is based upon a review of these documents.

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 generate thinking around the ethical issues related to social media research. http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/educationresources/social_media_workshop_july_16

There are many grey areas in social media research. Researchers should contact the UREC should they need advice on a specific research project.

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 data 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.

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.

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 EU General Data Protection Regulation (GDPR) (NB. Other laws may apply to research undertaken outside the EU)

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 user names 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)

For more guidance on data protection obligations, and what an appropriate legal basis may be, refer to the Research Ethics Policy Note no. 4 'Principles of Anonymity, Confidentiality and Data Protection'

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

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 standards of research quality and integrity 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 social media data.

Whilst this policy note only applies to use of social media data for research purposes (defined as "a process of investigation leading to new insights, effectively shared", some of the issues discussed may also be appropriate to consider for other non-research uses of social media data (e.g. marketing, public engagement etc).

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 be ethically approved prior to data being collected and analysed.

As argued by the British Psychological Association (2013) whether a post should be perceived 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' – to enter the group without the knowledge or consent of moderators and/or users would be deception
- Twitter users using a #hashtag to make their Tweets 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 not all social media users have a good understanding of how accessible their content is to others.

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 using social media are at a disadvantage in that they have no direct contact with the populations they are observing. 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, 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, consideration should be given to steps that 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 that 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 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.

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 harm.

As with all research, the sensitivity of the topic impacts upon ethical decision making, but in projects involving social media data 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.

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 in their research, 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, 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 should indicate the type of events that the researcher intends to research, and give in depth consideration to the type of data that may be used, issues of

anomymisation, consent, risk and sensitivity, the type of analysis to be conducted, and when/how findings are to be published (i.e. immediate publication online; delayed publication in 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 demand there is on the researcher to address these issues thoroughly.

6. IS INFORMED CONSENT REQUIRED?

Assuming consent is not being used as the legal basis for the processing of personal data according to the GDPR (in which case GDPR-compliant consent MUST be obtained), 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 Association (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 space 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)". This aligns with recommendations in a number of social media research ethics guidelines. 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 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, it may be appropriate to check that the terms and conditions of the platform state that the users have agreed to explicitly allow research use of data 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.

Dependent 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 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 social media users' preferences about the use of their data
- The researcher's level of engagement with the social media users (i.e. will they observe/analyse data without interacting, or will they engage directly with users?) (see Research Ethics Policy Note no.2 (Principles of Consent) with respect to consent in participant observation (section 7) and the Specialist Research Ethics Guidance Paper entitled 'Ethical considerations in autoethnographic research')
- The potential harm to the community if they become aware of a researcher observing their interactions (see British Psychological Association (2013) Principle 3: Social Responsibility p. 6)
- Whether the nature of the research means that it is appropriate to engage in covert observation of a non-public space (see Policy Note no. 2 (Principles of Consent) with respect to research involving principled deception (section 6))
- How practically 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 Tweet, Facebook message etc?)
- 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, the researcher may be unaware of the deletion and analyse it alongside other still existing data.

If a user deletes a comment this suggests 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, **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, as well as 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 been taken and shared. For example, for a stock image of a model, we can assume 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 in a protest, we cannot assume the individual has consented to the image being taken and shared, and furthermore its reproduction could cause harm to the individual in some social contexts.

How to anonymise social media data

- The researchers should only collect the identifying 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 identifying information (e.g. usernames) at the earliest opportunity. Remember that such datasets are often re-identifiable using the correct techniques, so they should still be treated as though they were identifiable data, and in line with the GDPR
- 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 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 that they paraphrase the quotation in a way that retains meaning. For higher risk research this should be standard practice. Advice on anonymization practices can be found here (British Psychological Society, 2013 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. Twitter states Tweets must be given in their original form and attributed to the individual who posted the Tweet. In such cases careful consideration needs to be given as to what is ethically appropriate.

8. DATA STORAGE, SHARING AND RE-USE

As with all research consideration needs to be given to how to store, share and archive social media datasets. As discussed above, potentially identifiable social media data is regulated under the 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 social media data providers 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, they may be a suitable alternative to downloading and storing data. However, such tools are not always transparent in relation to how data are collected, analysed and presented, which can raise separate research integrity and ethical issues as discussed in section 3 above.

References

British Psychological Association (2013). Ethics Guidelines for internet-mediated research. Available at: http://www.bps.org.uk/system/files/Public%20files/inf206-guidelines-for-internet-mediated-research.pdf

ICO (2014), Big Data and Data Protection. Available at: https://ico.org.uk/media/for-organisations/documents/1541/big-data-and-data-protection.pdf

IPSOS MORI (2015) #SocialEthics: A guide to embedding ethics in social media research. Available at: https://www.ipsos-mori.com/researchpublications/publications/1771/Ipsos-MORI-and-DemosCASM-call-for-better-ethical-standards-in-social-media-research.aspx

Townsend L. and Wallace C. (2016). Social Media Research: a guide to Ethics. Available at: www.dotrural.ac.uk/socialmediaresearchethics.pdf

The University of Sheffield
Research Ethics Policy Note no. 15

DEMONSTRATING THE IMPACT OF RESEARCH

The impact of research refers to an 'effect on, change to or benefit to the economy, society, culture, public policy or services, health, the environment, or quality of life, beyond academia' (definition taken from the UK Research Excellence Framework 2014). 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. In collecting the evidence required to demonstrate impact, 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 set out in the General Principles and Statements section of the Ethics Policy is 'a process of investigation leading to new insights, effectively shared'. Impact can be demonstrated in a variety of ways, and may involve seeking the opinion or recommendation 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).

Where data is collected from human participants specifically and solely for the purposes of evaluating the impact of a research project, and personal data* will only be used by members of the research team and, if required, a formal evaluation panel for assessment and reporting as part of a research evaluation process (e.g. as part of the UK Research Excellence Framework or similar), ethics approval will NOT be required.

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

(1) Where 'demonstration of impact' 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;
AND/OR
(2) Where data from 'demonstration of impact' activities will be made accessible to an audience beyond the research team (other than as part of a formal research evaluation process). 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 ethics approval is not required according to the above, care needs to be taken to ensure that people involved in evaluating the impact of a research project 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 organisations through their involvement in evaluating the impact of a research project.

*It should be noted that the UK Data Protection Act 1998 (or from 25 May 2018, the General Data Protection Regulation) 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.