



UNIVERSITY OF SHEFFIELD ETHICS POLICY FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, DATA AND TISSUE

1 OVERVIEW

1.1 INTRODUCTION

The University's central research ethics website:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/system.html

On 15 October 2003 the University of Sheffield's Senate approved the '*Ethics Policy for Research Involving Human Participants, Data and Tissue*' (the Ethics Policy). The University of Sheffield's Research Committee and Directors of Research recommend that all members of the University of Sheffield (the University), both staff and students, conducting or participating in research activities that involve human participants observe the University's Ethics Policy. A separate University policy exists for research involving animals.

The Ethics Policy has been developed in close consultation with senior University academics and administrators and has been prepared with reference to EU and UK legislation (e.g. EU Directive on Good Clinical Practice in Clinical Trials, the Data Protection Act 1998), professional guidelines (e.g. the British Psychological Society), and higher education documents (e.g. research funder publications, other University research-related policies).

The University is committed to advancing and safeguarding high quality academic and ethics standards in all its activities. Research undertaken in accordance with recognised research ethics principles constitutes good research practice. The Ethics Policy should be read in conjunction with the [University's Good Research Practice Standards](#) and with the [University's Procedure on Investigating and Responding to Allegations of Research Misconduct Against University Staff](#).

When undertaking research, researchers are expected to need to observe ethics principles. This is especially true for research activities that involve human participants, data and tissue or research activities that involve animals. The Ethics Policy clarifies the conditions under which research with human participants, data and tissue is acceptable.

1.2 DEFINITION OF RESEARCH ETHICS

In the context of the University's Ethics Policy/Ethics Review System, the University's definition of research is based upon the Research Assessment Exercise's definition of research, except that it also broadens this out to include supervised-student research.

'Research is to be understood as investigation undertaken in order to gain knowledge and understanding, including work of educational value designed to improve understanding of the research process. It also includes work of direct relevance to the needs of commerce and industry, as well as to the public and voluntary sectors; scholarship*; the invention and generation of ideas, images, performances and artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in

experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes 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. It also excludes the development of teaching materials that do not embody original research.

* Scholarship for the RAE is defined as the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases.”

Ethics derives from the Greek word *ethos*, meaning custom / mores / character. The actual concept of ethics is taken to define systems of moral principles or values, principles of right or good behaviour in relating to others, and the rules and standards of conduct binding together members of a profession.

The concept of research ethics marries the idea of undertaking investigations in order to gain knowledge and understanding (research) with the idea that such investigations must be undertaken in accordance with moral principles and values of right or good behaviour in relation to others (ethics). The concept can cover all types of research, from research involving animals and other living subjects to research involving the environment, and can be used to determine what types of research an organisation will support (e.g. organisational ethics). However, in the Ethics Policy the concept of research ethics is used in a more limited sense to apply to research involving human participants, data and tissue.

1.3 APPROACH

The University's approach has been to develop an Ethics Policy that recognises the University's distinct governance, culture and diversity while supporting the achievement of its collective research objectives. The Ethics Policy builds on existing good research ethics practice in the University and complements research ethics procedures in place in the National Health Service (NHS).

1.3.1 DIVERSITY

The University supports the diverse nature of its research base, recognising that diversity in research activities enriches and strengthens the University's research culture and climate. This diversity means that the significance of ethical issues relating to human participation in research differs considerably for each academic Department (Department), in large part because the proportion and volume of research activities involving human participants, data and tissue differs widely from one Department to another.

The Ethics Policy applies to all Research Divisions but has been designed to allow a certain degree of flexibility at the individual Department level in recognition of the diverse and dynamic nature of the University's research base. The decision regarding whether or not an individual research proposal involving human participants, data or tissue raises ethical concerns, and whether or not it requires ethics approval, is made on a case by a case basis within the parameters of the University's Ethics Review Procedure (see Section 3).

1.3.2 NHS RESEARCH ETHICS PROCEDURES

The Ethics Policy has been composed in such a way as to complement the current established NHS ethics review system. The University's Ethics Review Procedure (see Section 3) does not duplicate the functions or overlap with the remit of the NHS ethics review system.

Ethics review via the NHS ethics review system is required for research which involves:

- i. Patients and users of the NHS (this includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS and NHS patients treated under contracts with private sector institutions).
- ii. Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.
- iii. Access to data, organs or other bodily material of past and present NHS patients.
- iv. Foetal material and IVF involving NHS patients.
- v. The recently dead in NHS premises.
- vi. The use of, or potential access to, NHS premises or facilities.
- vii. NHS staff – recruited as research participants by virtue of their professional role.
- viii. Phase 1 studies involving healthy volunteers *

* The introduction of the EU Clinical Trials Directive (2001/20/EC) into UK law now means that 'Phase 1 studies involving healthy volunteers' (i.e. Clinical Trials of Drugs) must now be ethically reviewed via the NHS and, specifically, by an NHS Research Ethics Committee recognised to ethically review Clinical Trials applications.

Advice on ethics from an appropriate NHS Research Ethics Committee is required for research involving the above:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

(Source: Governance arrangements for NHS Research Ethics Committees (GAfREC), published by the Central Office for Research Ethics Committees (COREC) in July 2001)

1.3.3 TRENDS

A combination of several, significant developments over recent years strengthened the case to develop an Ethics Policy:

- i. A continuing research sponsor-driven trend towards ensuring that, where applicable, sponsored research is subject to prior ethics approval.
- ii. A continuing trend towards collaborative interdisciplinary and international research.
- iii. Developments in UK and EU legislation and policy concerning research ethics.
- iv. A series of well-publicised scandals that adversely affected public confidence in health and social care research (e.g. the Royal Liverpool Children's Hospital AlderHey Inquiry).
- v. The development of research ethics policies by other Russell Group Universities.

1.4 BENEFITS

Clear benefits to participants in research, individual researchers, Departments and the University are envisaged as a consequence of establishing an Ethics Policy. It will:

- i. Help protect the dignity, rights, safety and well being of human participants.
- ii. Codify the University's position on research ethics, for research involving human participants, data and tissue, legitimise its ethics review procedure and affirm its commitment to high ethics standards.
- iii. Provide a guide for both new and established staff.
- iv. Further embed a research culture based upon good research practice principles.
- v. Demonstrate a commitment to high-quality, transparent and accountable research ethics practices at project level.
- vi. Reduce risks to the University, Departments and individual researchers.
- vii. Strengthen the eligibility and quality of research applications.

- viii. Enhance the University's reputation in society, the academic profession, with funding bodies and auditors.

1.5 APPLICABILITY

The University's Ethics Policy is generic and applies to:

- i. All University researchers (members of the University – i.e. staff, registered students) who are conducting or contributing to research activities involving human participants, data and tissue which take place within or outside of University premises and facilities.
- ii. All individuals who are not members of the University but who are conducting or contributing to research activities involving human participants, data and tissue which take place within University premises and facilities.

Adherence to the Ethics Policy does not form part of the formal contract of employment for University staff, but it is a condition of employment that employees shall abide by the rules, policies and guidelines made by the University.

1.6 GOVERNANCE AND IMPLEMENTATION

Heads of Department are responsible for research performed in their departments and therefore for the application of and adherence to the Ethics Policy by departmental researchers who are conducting or participating in research activities that involve human participants, data or tissue. Individual researchers are expected to follow the leadership of their Head of Department.

1.7 REVIEW

On an annual basis, in the first instance, the University's Research Ethics Committee will undertake a review of the University's Ethics Policy and report its key findings and recommendations to the University's Senate.



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2 ETHICS PRINCIPLES FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, DATA AND TISSUE

2.1 INTRODUCTION

The University is committed to advancing and safeguarding high quality academic and ethics standards in all its activities. The University's Ethics Policy clarifies the conditions under which research with human participants, data and tissue is acceptable.

The Ethics Principles for Research Involving Human Participants, Data and Tissue (Ethics Principles) are intended to protect both participants involved in research activities undertaken by University researchers and the researchers themselves. The University expects all its researchers, conducting or contributing to research activities that involve participants, data and tissue to respect and uphold the Ethics Principles at all times throughout the lifetime of the research.

Section 3 of the Ethics Policy explains the University's Ethics Review Procedure, which is the University's Ethics Policy in practice.

2.2 GOOD RESEARCH PRACTICE

Research undertaken in accordance with recognised research ethics principles constitutes good research practice. The University's Ethics Policy should be read in conjunction with the [University's Good Research Practice Standards](#) and with the [University's Procedure on Investigating and Responding to Allegations of Research Misconduct Against University Staff](#).

Upholding Ethics Principles in the conduct of research means acceptance of and respect for principles of integrity, honesty and openness, characteristics of a good researcher. Conducting research with integrity exemplifies a commitment to intellectual honesty and acceptance of personal responsibility for one's own actions.

As part of treating participants with respect, research involving participants should constitute new investigations undertaken in order to gain knowledge and understanding and therefore investigations that should not have already been undertaken.

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

The primary responsibility for considering, respecting and safeguarding the dignity, rights, safety and well being of participants involved in research lies with the lead researcher (e.g. Principal Investigator, Supervisor).

Individual researchers are responsible to a range of stakeholders for their conduct in and delivery of their research activities:

- participants;
- society;
- fellow researchers (colleagues), their Department and the University;
- the research funder;
- the academic profession.

No University member of staff or University student should be compelled, or compel others, to undertake or participate in a research activity that conflicts with their own individual ethics principles.

2.3 DEFINITION OF HUMAN PARTICIPATION

From this point forward human participants are referred to as participants. Research involving participants is hence defined broadly to include research that:

- i. **Directly involves people** in the research activities, through their physical participation. Physical participation may signify invasive (e.g. surgery) and / or non-invasive research (e.g. interviews, questionnaires, surveys, observational research) and may mean the active or passive involvement of a person.
- ii. **Indirectly involves people** in the research activities, through their provision of or access to personal data and / or tissue.
- iii. **Involves people on behalf of others** (e.g. parents / legal guardians of children and the psychologically and / or physically impaired, and supervisors of people under controlled environments (e.g. prisoners, pupils)).

The nature of participation in research and the degree of commitment and intensity of effort that may be requested, subject to their consent, will vary from one research project to another. At one end of the spectrum people may be involved in invasive research as patients (e.g. surgery) whereas, at the other end of the spectrum, people may be involved in non-invasive research (e.g. interviews, questionnaires, observational research).

The Ethics Policy uses the Data Protection Act's (1998) definition of personal data:

"Data which relates to a living individual who can be identified from those data, or from those data and other information which is in the possession of, or is likely to come into the possession of, the data controller, and includes any expression of opinion about the individual and any indication of the intentions of the data controller or any other person in respect of the individual".

'Sensitive' personal data consists of information as to:

- i. The racial or ethnic origin of the data subject,
- ii. His or her political opinions,
- iii. His or her religious beliefs or other beliefs of a similar nature,
- iv. Whether he or she is a member of a trade union (within the meaning of the Trade Union and Labour Relations (Consolidation) Act 1992),
- v. His or her physical or mental health or condition,
- vi. His or her sexual life,
- vii. The commission or alleged commission by him or her of any offence, or

- viii. Any proceedings for any offence committed or alleged to have been committed by him or her, the disposal of such proceedings or the sentence of any court in such proceedings'
(Source: Part I, Preliminary of the Data Protection Act 1998)

The Ethics Policy uses the 2004 Human Tissue Act's definition of human tissue:

'Relevant material that has come from a human body and consists of, or includes, human cells'. Detailed fact-sheet:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

2.3.1 PARTICULARLY VULNERABLE PARTICIPANTS

Some people participating in research may be more particularly vulnerable to harm than others. **Particularly vulnerable groups include:**

- i. Infants and children under the age of eighteen;
- ii. People with physiological and / or psychological impairments and / or learning difficulties;
- iii. People dependant on the protection or under the control or influence of others (e.g. children, pupils, people in care, young offenders, prisoners, employees/fellow staff, students);
- iv. Relatives of sick people (e.g. parents of sick children);
- v. People who may have only a basic / elementary knowledge of the English language.

Researchers should be especially sensitive to the need to consider, respect and safeguard the dignity, rights, safety and well being of particularly vulnerable people participating in their research.

2.4 ETHICS PRINCIPLES FOR RESEARCH INVOLVING PARTICIPANTS

2.4.1 FUNDAMENTAL ETHICS PRINCIPLES AND GOVERNANCE

However humanitarian the motive of a researcher for undertaking a particular piece of research may be, any research that involves people as participants produces potential risks in terms of infringement or invasion of their dignity, rights, safety or well being.

The fundamental principles that govern University research involving participants are enshrined in the Council of Europe's '*Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*':

www.conventions.coe.int/Treaty/en/Treaties/html/164.htm

In 2005 the UK Council for Science and Technology published '*Rigour, respect and responsibility: A Universal ethical code for scientists*' (a public statement of the values and responsibilities of scientists and aims to foster ethical research):

www.cst.gov.uk/cst/business/files/ethical-code.pdf

People participating in research have, at the very least, all the rights as defined by law (e.g. the 'Human Rights Act 1998', the 'Data Protection Act 1998', and relevant European Directives and Conventions). The United Kingdom is not a signatory of all conventions relevant to research ethics, or the UK demurs from specific provisions within some conventions. However, as statements of widely accepted ethics standards, researchers, the University Research Ethics Committee, University Ethics Review Panels and University-accredited ethics reviewers may also refer to such documents for guidance.

Research projects may, as a reflection of the diversity of modern society, involve people from a variety of cultures and ethnicities, professing to a variety of different creeds and political beliefs. They may also involve people of different backgrounds in terms of age, disability, gender, and sexual orientation. Researchers need to consider carefully the ethics implications of the design and methodology of their research in order to address, in a sensitive and appropriate way, the nature and needs of the participants and in order to ensure that any foreseeable harm is prevented.

2.4.2 SAFETY AND WELL-BEING

Detailed fact-sheet: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

Researchers have a responsibility to protect participants from any harm arising from research. As a general rule, people participating in research should not be exposed to risks that are greater than or additional to those they encounter in their normal lifestyles. If it is expected that harm, unusual discomfort or other negative consequences might occur in the prospective participant's future life, as a result of participating, the lead researcher must, prior to the person's participation, obtain:

- i. The disinterested approval of and informed consent of independent, accredited ethics reviewers (e.g. University ethics reviewers; NHS Research Ethics Committee);
- ii. The informed consent of the prospective participant.

Depending on the nature of the research, researchers have a responsibility to ask participants about any factors in the research, such as pre-existing medical conditions, that might create risks to them if they participate, and they must subsequently be advised of any special action they should take to avoid risk.

Before participating, people should be informed of procedures for contacting the lead researcher within a reasonable time period if, following participation, they experience stress, harm or have related concerns.

If during research a researcher obtains evidence of physical or psychological problems of which a participant is, apparently, unaware, 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 endangered. However, if the issue is serious and the researcher is not qualified to offer assistance, then the 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 (trial subjects / patients) are usually 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 (e.g. 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 to withdraw, a right to be harmed, in exceptional circumstances, as well as for harm to be prevented.

In the case of non-invasive research methods such as interviews and questionnaires, the content and line of questioning may be highly sensitive, raise confidential, personal issues and intrude, or be perceived to intrude, upon a participant's comfort and privacy. The initial judgment on whether or not questions are sensitive and likely to cause harm rests with a

lead researcher. For advice the lead researcher should initially consult the person who has been designated as the Ethics Administrator for his/her Department.

2.4.3 PRINCIPLE OF CONSENT

2.4.3.1 OBTAINING CONSENT

Detailed fact-sheet: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

Prior to a person being able to participate in research activities the lead researcher is responsible for obtaining that person's consent to participate. Consent must be given freely and voluntarily and under no circumstances must coercion be used to obtain a person's consent to participate in research. Wherever possible, and proportionate to the nature of the research activity, an individual's consent should be obtained in writing. Where this is not possible oral consent should be obtained, ideally in the presence of at least one witness. Witnessed consent is required for particularly vulnerable participants who have intellectual or cultural difficulties in speech or understanding, but who are deemed capable of giving consent (see Section 2.3.1).

Researchers should make plain to people, prior to their participation, their explicit right to refuse to participate in and / or to withdraw from the research at any stage, irrespective of whether or not payment or other inducement has been offered, and that this right will be respected.

2.4.3.2 INFORMED CONSENT

Informed consent is where a prospective participant, prior to participating in research:

- i. Is fully informed about all aspects of the research project, in which s/he is considering participating, that might reasonably be expected to influence his / her willingness to participate. In addition, the researcher should normally explain all other aspects of the research about which the prospective participants enquire. Such aspects will include some or all of the following:
 - the nature and objectives of the project;
 - the methodology of the project and conditions for conducting it;
 - who is undertaking and who is sponsoring the project;
 - the potential risks and inconveniences that may arise;
 - the potential benefits that may result;
 - what participation in the research will require;
 - (in the case of medical research) alternative treatments.
- ii. Freely and voluntarily gives consent to participating.

Giving and obtaining consent is usually a process, not a one-off event and participants have the right to change their minds and withdraw consent at any time. If a researcher doubts whether a person participating in research still consents to participating s/he should clarify this with the person in question.

If the prospective participant is, for any reason, unable to understand the implications of participation, then the researcher is responsible for obtaining the informed consent of the parents / legal guardians of the prospective participant. Special care should be exercised in such cases.

Where University accredited ethics reviewers or a University Ethics Review Panel or the University Research Ethics Committee or an external Research Ethics Committee (e.g. in the NHS) has specifically instructed a researcher to obtain the informed consent of

participants, or where a research funder specifies, as a condition of its award, that informed consent be obtained from participants in the research, then informed consent must be the obtained standard.

2.4.3.3 COERCION

The quality of the consent of participants who are in a potentially dependent relationship with the researcher (e.g. employees, patients, students) requires careful consideration, as willingness to volunteer may be unduly influenced by the expectation of benefits or rewards.

When research is being conducted with detained persons (e.g. prisoners) particular care should be taken over informed consent, paying particular attention to the special circumstances that may affect the person's ability to freely and voluntarily give informed consent.

People volunteering to participate in research may be paid for their inconvenience and time. Payments made to individuals, to enable them to participate in research activities, must not be so large as to induce the individuals to risk harm beyond that which they would usually undertake. Financial payments might cover reimbursement for travel expenses and / or time. Risks resulting from participation should be acceptable to participants even in the absence of inducement.

The promise of compensation and care for damage, injury or loss of income as a result of participating in research activities to participants should not be considered coercion by inducement.

2.4.3.4 RESEARCH INVOLVING INCOMPETENT ADULTS

Where a prospective participant e.g. clinical trial subject / patient, is unable to give informed consent to participate a 'legal representative' may give assent on his / her behalf. Such a 'legal representative' should be able to give assent for and authorise an intervention on the patient. In the case of a child, such a person would have parental responsibility (i.e. parent / legal guardian).

In the case of an adult this could be a person designated by the adult, a relative or an independent person nominated by, for example, the hospital at which the research is being undertaken. If the adult has appointed a representative who is available, then this person must be used to give assent. A relative can only be used if the person has not appointed a representative or if the representative is not available. An independent person should only be used if both the adult's representative and a relative are not available. Consequently, an independent person should only be used to give assent on an adult's behalf where the research cannot be conducted if there is delay (i.e. research in an emergency situation), where the person whose representative or relative is not available is indispensable for the research, and where the research is of sufficient importance to justify the giving of assent on behalf of the adult concerned. In such cases the independent person, responsible for the care of the adult, cannot be used if s/he is involved in the research or has any direct interest in it.

2.4.3.4.1 CLINICAL TRIALS OF MEDICINAL PRODUCTS

Where a prospective vulnerable adult is unable to give informed consent to participate a 'legal representative' may give assent on his / her behalf.

2.4.3.5 RESEARCH INVOLVING CHILDREN

If the involvement of infants and children under the age of eighteen in a research project is justified, where appropriate and feasible the informed consent of one of their parents or their legal guardian should be obtained for inclusion of the child in the research. 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 unfeasible (e.g. research involving homeless children).

Wherever possible, a researcher seeking to undertake research with children under the age of eighteen should also obtain the child's free and voluntary consent to participate. However, the ability of a child to give free and voluntary consent depends very much on a child's level of competence and competence varies with age. Other factors include the child's own experience and confidence, the type of research s/he is being invited to participate in, and the skill with which a researcher talks with as child and helps that child to make free and voluntary, informed decisions.

In both invasive and non-invasive research, where a child under the age of eighteen is participating in research, unless a parent / legal guardian is not available and unless it can be sufficiently demonstrated that the research in its entirety is in the best interests of the children, researchers should obtain the informed consent of both a parent / legal guardian and the child.

Within the NHS, the Patient Information Advisory Group (PIAG) has the authority to override the need for consent where it is unfeasible, under section 60 of the Health & Social Care Act (e.g. PIAG 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 of CJD).

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

2.4.3.5.1 CLINICAL TRIALS OF MEDICINAL PRODUCTS

Children aged 16 and older can legally consent for themselves in relation to clinical trials. However, this does not apply to clinical trials of devices.

2.4.3.6 RESEARCH INVOLVING DECEPTION

In certain research disciplines (e.g. psychology), to ensure the viability of a piece of research, to ensure that it will contribute to knowledge and understanding, it is sometimes necessary to withhold information on the true objectives of the research from the people participating in it. In such types of research 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 them. However, when such research, requiring consent but not informed consent from participants, is judged to be necessary for the results of the research to be valid, researchers should exercise particular caution. In such circumstances the lead researcher has a special responsibility to:

- i. Justify that alternative procedures to avoid the withholding of information or deliberate deception are not available and, if available, are not feasible for the research;
- ii. Justify why the withholding of information, or an element of concealment or deception, is integral to the viability of the research.

2.4.3.7 RESEARCH IN PUBLIC CONTEXTS AND WITH GROUPS

In certain types of research obtaining consent from every individual participating is impractical or unfeasible (e.g. observing a large crowd or observing discussions on the internet). In such types of research researchers should ensure the following:

- i. That such research is only carried out in public contexts;
- ii. That where possible approval is sought from relevant authorities;
- iii. That appropriate individuals are informed that the research is taking place;
- iv. That no details that could identify specific individuals are given in any reports on the research unless reporting on public figures acting in their public capacity (e.g. reporting a speech by a named individual);
- v. That particular sensitivity 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.

The privacy and psychological well-being of people participating in observational research and people participating in research activities in which a 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 at any stage. However, in such types of research, researchers are expected to make a reasonable attempt to do so.

2.4.4 PRINCIPLES OF ANONYMITY, CONFIDENTIALITY AND DATA PROTECTION

Detailed fact-sheet: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

The collection, storage, disclosure and use of research data by researchers must comply with the 1998 Data Protection Act.

Arrangements should be prepared by researchers to carefully protect the confidentiality of participants, their data and/or tissue. All personal information collected should be considered privileged information and be dealt with in such a manner as not to compromise the personal dignity of the participant or to infringe upon their right to privacy.

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

- i. Any potential risks that might mean that the confidentiality or anonymity of personal information may not be guaranteed.
- ii. Which individuals and organisations, if any, will be permitted access to personal information, and under what circumstances such access will be permitted.
- iii. The purpose for which personal information provided is to be used (e.g. if video material might be used for teaching purposes), unless Section 2.4.3.6 applies.

Researchers must assure participants that any personal information collected, that could identify them, will remain strictly confidential and, depending on the research, access to the information will be restricted to the lead researcher or to researchers directly involved

in the research at all times, before, during and after the research activities. In certain types of research, where necessary and practical, personal information on participants, that could identify them, will remain anonymous at all times, even to the researchers themselves.

A researcher may not disclose the identity of a person nor disclose any information that could identify that person without having obtained, prior to the person's participation, the person's consent in writing. If it is necessary, to a piece of research, to identify participants explicitly, then the researchers should explain why this is the case and how confidentiality will be protected.

Researchers should be aware of the risks to anonymity, confidentiality and privacy posed by all kinds of personal information storage and processing which directly identify a person (e.g. audio and videotapes, electronic and paper-based files, e-mail records). Measures to prevent accidental breaches of confidentiality should be taken, and in cases where confidentiality is threatened, relevant records should be destroyed. Provisions for data security at the end of a project must be made. (see University Good Research Practice Standards, Sections 3.7.2 – 3.7.4).

All participants have the right to access personal information, whether or not it is confidential, that relates to them, and to be provided with a copy of the information on request.

People should have the right, following the completion of their period of involvement in the research and following discussions with the researcher, to withdraw their consent and to require that their own data be destroyed, if practicable.

2.4.4.1 ANONYMISATION

Wherever possible data should be collected, stored or handled in anonymous form. Where linkage between datasets is required, e.g. in longitudinal studies, record numbers should be used as far as possible, with special measures used to protect the key that would link a number to personal identifiers.

Name and address are not the only way of identifying an individual. There are other forms of information that can be used to identify an individual, e.g. date of birth or clinical diagnosis for rare diseases, especially if the area covered by a dataset is small. Similarly the keys for some record numbers e.g. NHS number, are easily accessible. Thus while removing name and address provides a 'first-line' protection of privacy, identification of the data subject may still be possible.

Considerable confusion exists about the effect that anonymising personal information/data has on the legitimacy of processing information that it contains. Recital 26 of the Data Protection Directive (95/46/EC) (which the UK's 1998 Data Protection Act implements) states that the principles of protection do not apply to data that has been rendered anonymous. However, data is only rendered anonymous for these purposes if it is no longer possible to identify the data subject from it directly or indirectly (Article 2(a) of the Directive). Hence, data that is coded or that is still held in personally identifying form, to which the depersonalised data can be linked, remains personal data for the purposes of UK data protection and cannot be considered rendered anonymous in the terms of Recital 26 of the Directive. One of the most important consequences of this relates to the duties of data controllers to inform research participants of the uses that will be made of personal data they provide. Bearing in mind that anonymisation is itself a process performed on personal data, it seems to follow from the EC Directive and the 1998 Data Protection Act, that those who obtain personal data from the data subject must inform the data subject of

what they intend to do with the information contained in the data after it has been rendered anonymous, and indeed of the intention to anonymise it and the consequences thereof.

Those who have received information in depersonalised form, other than from the data subject, so that they cannot identify the data subject obviously cannot discharge their duties to inform the data subject under the 1998 Data Protection Act (Schedule I Part II paragraph 2) or the Directive (Article 11). However, those from whom they obtain this information have a duty to inform them of any restrictions on the use of this information that has been placed on it by the data subject, with which they must comply (see Section 55 of the 1998 Data Protection Act).



UNIVERSITY OF SHEFFIELD ETHICS POLICY FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, DATA AND TISSUE

3 UNIVERSITY ETHICS REVIEW PROCEDURE FOR RESEARCH INVOLVING HUMAN PARTICIPANTS, DATA AND TISSUE

3.1 INTRODUCTION

The University's Ethics Review Procedure ('Ethics Review Procedure') is the University's Ethics Policy in practice.

3.1.1 APPLICABILITY

All University members of staff and University registered students (i.e. postgraduate, postgraduate taught and undergraduate) who plan to undertake research which involves participants and / or their data and / or their tissue need to obtain ethics approval for the planned research, prior to the involvement of the participants, via the appropriate ethics review procedure (see Section 3.3. below). See Section 2.3 of the Ethics Policy for the definition of human participant. **The primary responsibility for considering, respecting and safeguarding the dignity, rights, safety and well being of participants involved in research lies with the lead researcher (e.g. Principal Investigator, Supervisor).**

The Ethics Review Procedure also applies to individuals who are not members of the University but who are carrying out such research involving participants, their data or tissue, on University premises.

The Ethics Review Procedure operates to protect participants in research, the researchers themselves and the University and has been structurally designed to:

- i. Ensure that, as a minimum, every University researcher and academic department has access to a University recognised ethics review mechanism;
- ii. Be sufficiently flexible to accommodate the diverse research interests and needs of academic departments while sufficiently coherent in design and operation to ensure corporate consistency.

It is envisaged that the University's research ethics arrangements will be competent, efficient, independent and transparent.

The appropriateness, relevance and significance of research ethics as an issue (i.e. in respect to research involving participants) will differ for each individual Department, being largely determined by the proportion and / or volume of their research activities that involve participants.

3.2 GENERIC STANDARDS

All research activities that involve participants and / or data and / or tissue are governed by the following generic standards. Such research activities:

- i. Fall within the remit of the Ethics Policy and, thereby, within the remit of the Ethics Review Procedure;

- ii. Are subject to ethics review, prior to the involvement of participants:
 - either via the University's ethics review procedure or;
 - via the *NHS* ethics review procedure or;
 - *via an alternative* ethics review procedure.
- iii. Require ethics approval via the appropriate ethics review procedure (i.e. University; or NHS; or alternative); prior to the involvement of participants;
- iv. Cannot commence research involving the participants until ethics approval via the appropriate ethics review procedure has been given;
- v. Cannot continue if ethics approval has been withdrawn or suspended;
- vi. Must comply with the conditions set by University accredited ethics reviewers or by a University Ethics Review Panel or by the University Research Ethics Committee or by an external Research Ethics Committee (e.g. NHS);
- vii. Must be notified to the University's Research Office (i.e. the Research Office should be informed of all 'ethics review outcomes' – the Department's Ethics Administrator provides information on an annual basis).

3.3 ETHICS REVIEW PROCEDURES

There are three potential routes through which to apply for ethics approval:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

3.4 MONITORING THE UNIVERSITY'S ETHICS REVIEW PROCEDURE

The U-REC reserves the right to monitor the University's ethics review procedure (administered locally by Departments) as and when required and, as a minimum, will contact Departments on an annual basis for an annual report of key activities and findings over the preceding twelve months.

3.5 UNIVERSITY RESEARCH ETHICS COMMITTEE (U-REC)

The U-REC meets a minimum of four times a year and on an ad hoc basis as necessary, and reports to Senate at regular intervals.

3.5.1 U-REC TERMS OF REFERENCE

The U-REC is responsible for:

- i. The ongoing review of the University's 'Ethics Policy for Research Involving Human Participants, Data and Tissue', including providing guidance on its interpretation;
- ii. Embedding the University's Ethics Review Procedure, which includes:
 - accrediting the ethics review arrangements in place within academic departments and reviewing accreditation on a five yearly basis;
 - monitoring the ethics review arrangements in place within academic departments, which includes reviewing ethics decision making reports from academic departments on an annual basis;
 - providing guidance on cases of uncertainty brought to its attention by academic departments' ethics review panels and for making decisions on cases that cannot be resolved by ethics review panels;
 - hearing appeals against the decisions made by academic departments' ethics review panels (the Committee can overrule the decisions of ethics review panels);

iii. Promoting awareness and understanding of ethical issues in research throughout the University's research community (i.e. ethical issues that are relevant to research that involves human participants and also ethical issues that are relevant to other types of research);

iv. To provide advice on any ethical matters relating to research that are referred to it from within the University;

v. Keeping abreast of new externally-driven developments, policies and regulations concerning research ethics and, where appropriate, ensuring that the University meets all necessary requirements

Members of the U-REC must adhere to the U-REC's Terms of Reference. Any changes to the Terms of Reference require the approval of Senate.

3.5.2 U-REC MEMBERSHIP

Position:	Name:
Chair (who is a University employee)	Professor Richard Jenkins
Secretary:	Mr Richard Hudson
Minute Secretary:	Ms Lindsay Cooper

Six employees of the University appointed by the Senate:

Deputy Chair	Dr Wendy Baird
Senate representative for the Faculty of Arts and Humanities	Dr Nicola Dibben
Senate representative for the Faculty of Science	Dr Lynda Partridge
Senate representative for the Faculty of Engineering	Ms Elena Rodriguez-Falcon
Senate representative for the Faculty of Medicine, Dentistry and Health	Dr Chris Newman
Senate representative for the Faculty of Social Sciences	Dr Peter Bath

Four lay members (who are neither employees nor students of the University):

Lay member	The Venerable Robert Fitzharris
Lay member	Dr Peter Allmark
Lay member	Ms Penelope Lewis
Lay member	VACANCY

Other:

Ex-Officio:	Professor Richard Jones
Students Union student representative	Ms Louise Docherty
Co-opted member	Professor Aurora Plomer

The U-REC may co-opt additional members as and when required.

3.5.3 U-REC OPERATIONAL MECHANISMS

The U-REC will:

- i. On an annual basis, receive reports from Departments summarising applications received, reviewed and/or registered;
- ii. On a five yearly basis, review the accreditation of University ethics review procedures administered by Departments.