

Research Ethics Policies and Procedures

2nd Edition March 2004



Sheffield Hallam University

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SHEFFIELD HALLAM UNIVERSITY

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SHEFFIELD HALLAM UNIVERSITY

Research Ethics Policies and Procedures 1

1 Coverage

- 1.1 This policy and associated procedures apply to all research undertaken under the auspices of the university. Any research undertaken by staff or students (undergraduate or post graduate) of the University which involves direct contact with patients or healthy participants, whether clinical, biomedical or social research, or the secondary use of existing human and animal materials or specimens, or where there may be any other ethical issues, should be subject to ethical review.
- 1.2 Responsibility for undertaking the review will depend on the nature of the research. While demonstrating that ethical scrutiny of research projects has occurred is the responsibility of supervisors or principal investigators, under the university self-regulation policy not all research projects will need to be formally approved by a committee.
- 1.3 All research by staff or students which involves National Health Service (NHS) staff or patients or is conducted on NHS premises is subject to NHS Research Governance procedures. Researchers and supervisors must consult the NHS Research Governance Framework and complete the paperwork specified by their local NHS Committee. This includes a detailed research protocol, which must be submitted to the relevant SHU Faculty Research Ethics Committee for methodological evaluation and any required changes must be undertaken before it is submitted to the local NHS committee. This research quality evaluation is a requirement of the NHS Research Governance Framework. Failure to comply with this will lead to delays as NHS committees will not process applications until such scrutiny has occurred. Specific procedures for the ethical scrutiny of undergraduate student research projects involving NHS patients, staff or for research conducted on NHS premises are currently under development by the Department of Health.

2 Guiding Principles

- 2.1 Research undertaken by staff and students must conform to all legal requirements. This will include compliance with relevant data protection legislation, appropriate screening of researchers working with vulnerable groups and strict adherence to licensing requirements for any animal or biomedical research.
- 2.2 Research should be undertaken in accordance with commonly agreed standards of good practice such as are laid down in the Declaration of Helsinki. These fundamental and widely accepted principles may broadly be categorised as:

- Beneficence – ‘do positive good’
- Non-Maleficence – ‘do no harm’
- Informed Consent
- Confidentiality/ Anonymity

All research must conform to

2.3 *Beneficence and Non-Maleficence*

Terms such as risk, harm and hazards include emotional and mental distress, and possible damage to financial and social standing, as well as to physical harm.

- The research should be scientifically sound and the purpose should be to contribute to knowledge;
- The research should be undertaken and supervised by those who are appropriately qualified and experienced;
- The importance of the objective should be in proportion to the inherent risk to the participant. Concern for the interests of the participant must always prevail over the interests of science and society;
- The research should be preceded by careful assessment of predictable risks in comparison with foreseeable benefits to the participants or to others;
- Research should not be undertaken where the hazards involved are not believed to be predictable;
- Adequate facilities and procedures should be in place to deal with any potential hazards.

2.4 *Informed Consent*

- Each potential participant must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the research and any discomfort it may entail;
- Any documentation given to potential participants should be comprehensible and there should be an opportunity for them to raise any issues of concern;
- Consent should be required in writing and records of consent should be maintained;
- Potential participants must be informed that they are free to withdraw consent to participation at any time;
- There should be a procedure for making complaints and participants should be made aware of this;
- All participants should be volunteers. Considerable care should be taken where consent is sought from those in a dependent position and it should be made clear that refusal to participate will not lead to any adverse consequences. For example, students must be assured that any decision not to participate will not prejudice in any way their academic progress;
- Any inducement offered to participants should be declared and should be in accordance with appropriate guidelines;
- Consent must be obtained from a legal guardian in the case of minors or any others who do not have the legal competence to give informed consent.

2.5 *Confidentiality/ Anonymity*

- All research should conform with legislation relating to data protection;
- Details that would allow individuals to be identified should not be published, or made available, to anybody not involved in the research unless explicit consent is given by the individuals concerned, or such information is already in the public domain;
- All reasonable steps should be taken to ensure that confidential details are secure;
- Great care must be taken where there is an intention to use data collected for one study, for another study. It is important that relevant guidelines are followed.

2.6 This guidance is only intended to be an introduction to the issues and an indication of the matters that will be considered by University ethics committees. A list of further guidelines and codes of practice is available via the Research Support Website at: <http://ntphoenix.adc.shu.ac.uk/enterprise/research/ethics/default.asp> or from the Secretary to the University Research Ethics Committee (see below). In addition, Faculties should make researchers aware of guidance that relates to particular disciplines and professions.

3 **Authority**

3.1 The ultimate responsibility for the care of human participants rests with the researcher. However, in discharging its duty the University has established a University Research Ethics Committee and empowered Faculties to establish their own research ethics committees (delegated committees). In addition, where appropriate, decisions are referred to NHS ethics committees.

3.2 The researcher has the responsibility for deciding what authorisation, if any, should be sought. If researchers are in doubt as to what is appropriate they should seek advice. However, it is possible to give a general indication, as follows:

3.3 *Self - Regulation*

There are a number of straightforward procedures where it may not be necessary for researchers to seek ethics committee approval. However, in these cases the researcher still has a responsibility to consider ethical issues and take note of any relevant codes of practice. Procedures which may come under this category include:

- Questionnaires and interview schedules where there are no major issues relating to confidentiality or sensitive information or controversial subject matter and vulnerable participants;
- Research already granted permission by other ethics committees;
- Procedures authorised by delegated committees as being appropriate for self-regulation.

3.4 However, where there is any doubt about any ethical issues relating to the project, it should be referred to the most appropriate delegated committee. Also

researchers should seek advice from more experienced colleagues, within or outside the University.

- 3.5 It is important to note that consideration by an ethics committee does not replace other procedures and advice relating to insurance cover, contract authorisation and health and safety issues.

3.6 *Delegated Committees*

Faculties are required to have procedures in place for dealing with research ethics issues. The number of committees within each faculty will depend on the range of the research within that faculty. It is the responsibility of the Faculty Research Ethics Committee(s) to ensure that all projects are appropriately scrutinised.

It is the responsibility of these delegated committees to develop their own terms of reference and procedural guidelines for approval by the University Research Ethics Committee. Faculty Research Ethics committees may be sub committees of the Faculty committees responsible for Research and Business Development. If this is the case reporting relationships should be administered accordingly.

The University Research Ethics Committee shall:

- approve the terms of reference, membership, policies and procedures of the delegated committees;
- act as an appeal body for delegated committees;
- monitor the activities of delegated committees through the receipt of annual reports, minutes of all meetings and other reports as appropriate;
- issue clear instructions and guidelines to the delegated committees on the standards of support and record keeping required.

- 3.7 In the first instance, all projects requiring ethics committee approval should be submitted to the delegated faculty committee. The University Research Ethics Committee may act as a 'court of appeal' in difficult cases.

3.8 *External Research Ethics Committees for Research Involving Human Participants*

In some cases approval must be obtained from an NHS, or other ethical committee. NHS approval will be required for any research project that involves:

- NHS patients and staff: people recruited as participants by virtue of current or past contact with NHS services including those being treated under contract with private sector providers;
- use of, or access to, NHS premises or facilities;
- access to records of previous or former NHS patients;
- clinical trials

- 3.9 It is essential that the delegated committees maintain a record of any application to an NHS, or other medical, ethical committee and the related decision.

4 Research Involving Animals

The use of animals is tightly governed and monitored by law and by the Home Office, specifically under the Animals (Scientific Procedures) Act 1986 and its accompanying codes of practice and processes. Researchers using animals should operate in accordance with these.

5 University Research Ethics Committee

5.1 Terms of Reference

5.1.1 *Scope and Status*

- For the purposes of these terms of reference, ethical considerations and conduct will include, but not be limited to, research involving human participants, research using animals, research integrity and the sources of research funding.
- The purview of the Committee will include research undertaken by both staff and students (undergraduate and postgraduate).
- The Committee is a sub-committee of the Research and Business Development Committee.

5.1.2 *Guiding Principles*

The Committee shall:

- operate procedures no less rigorous than those suggested or required by relevant statutory or professional bodies;
- be impartial, supportive, developmental and dedicated to the promotion of ethical standards in research;
- ensure that proposals are scientifically sound without making judgements on quality as many projects are undertaken within a learning environment
- consider, taking specialist advice where required, on the insurance, liability and other legal implications of activities.

5.1.3 *Activities*

- To recommend to the Research and Business Development Committee and Academic Board policies and procedures for the ethical conduct of research.
- To advise University bodies staff and students, as appropriate, on all matters pertaining to the ethics of research.
- To issue guidelines and codes of practice, where appropriate on any matter pertaining to research ethics.
- To recommend the necessary administrative arrangements for operating the policies and procedures,
- To approve the terms of reference, membership, policies and procedures of delegated committees.
- To act as an appeal body for delegated committees.
- To monitor the activities of delegated committees.
- To liaise with external research ethics committees, in particular those established by the NHS.

- To subject its own activities to continuous review and present an annual report on its activities to the Research and Business Development Committee.
- To raise awareness of research ethics amongst staff and students across SHU.

5.2 Membership

5.2.1 The Research and Business Development Committee, taking advice as may be appropriate, shall appoint members to the Research Ethics Committee, which shall include:

- A Chair who shall have knowledge and experience of both research ethics and at least one of the areas of research likely to be considered by the Committee. The Chair will be an ex-officio member of the Research and Business Development Committee;
- Representatives from all the Faculties at SHU who should be active researchers with knowledge of research ethics. Membership should represent the range of research disciplines across each faculty.
- One member of staff of the University who has knowledge and experience of moral, philosophical or related issues e.g. a member of the University multi faith chaplaincy;
- One person who is independent of the University, with knowledge and experience of moral, philosophical or related issues.
- A Secretary who will normally be a member of the Research Support Office.

5.2.2 All members shall be appointed for three years in the first instance.

5.2.3 The Committee shall elect a Vice – Chair from within its membership.

5.3 Quorum

Four members, including either the Chair or Vice-Chair, have to be present.

5.4 Frequency of Meetings

The Committee shall meet at least four times a year in cycle with meetings of the Research and Business Development Committee.

SAFEGUARDING INTEGRITY IN RESEARCH AND DEALING WITH ALLEGATIONS OF MISCONDUCT IN RESEARCH

(Research Ethics Policies and Procedures: 2)

1 Introduction

- 1.1 In the wake of recommendations made by an international committee¹ for the safeguarding of scientific integrity, a number of UK and international research funding bodies have sought to impose guidelines on recipients of research funding. Following the US example, the Association of Medical Research Charities, the UK Research Councils², and the Wellcome Trust,³ amongst others, have mandated the adoption of self-regulatory codes of scientific practice broadly based on the above recommendations, by research organisations in receipt of their funds. Many have also issued specific recommendations related to their fields and indicated that sponsorship will be conditional upon the implementation of key elements of the code within recipient organisations. Indeed, some have stated that sanctions will be imposed on those that fail to do so. The principles are also applicable other areas of research and the terms 'scientific misconduct' and 'research misconduct' are used interchangeably in this document.
- 1.2 There is little evidence of significant occurrence of scientific misconduct in the UK. Nevertheless, in addition to the importance of satisfying research funding bodies, it is also incumbent on universities to train and develop both new staff and students in good research practice.
- 1.3 Furthermore, the potential for scandal that can surround the incidence, or alleged incidence of, scientific misconduct suggests that it would be prudent for the University to have in place procedures designed to minimise the negative impact of such an occurrence. Therefore, this paper also draws on a wide consensus across the UK research sector for proposals in respect of good practice for dealing with scientific misconduct, should this occur.
- 1.4 Consequently, this policy is divided into two sections:
- The Principles of Integrity in Research
 - Procedures for dealing with Allegations of Research Misconduct.

Section 1 applies to all research undertaken by the University, including research undertaken by students. However, section 2 does not apply to allegations of research misconduct against students, including research students, which will be dealt with in accordance with the Cheating Regulations for students. In cases where members of staff are also registered for research degrees, the appropriate procedure will be determined by whether or not the research in question is related primarily to the research degree.

¹ Commissioned by Deutsche Forschungsgemeinschaft (the German Research Association)

² Director General of the Research councils and the Chief Executives of the Research Councils.

Section 1 Principles of Integrity in Research

1.1 Good research practice includes:³

Fundamentals of research work such as:

- *maintaining professional standards;*
- *documenting results;*
- *questioning one's own findings;*
- *attributing honestly the contribution of others;*
- *Leadership and co-operation in research groups;*
- *Taking special account of the needs of new researchers; and*
- *Securing and storing primary data.*

1.2 These principles should be widely disseminated within the University and should be integrated into academic teaching, research training of post-graduate students and training of research supervisors and research managers. These principles, and those elaborated below, are supplementary to standards issued by professional societies and to international standards such as the Helsinki Declaration and the University's Ethics Policy for research involving human participants.

2 Leadership and Organisation

It is the responsibility of the University's senior management, Executive Deans of Faculties and Directors of Research Institutes and Centres to ensure that a climate is created that allows research to be conducted with the principles of good research practice.

Whilst adherence to principles of good research practice is the responsibility of each individual, the University and each of its research units has a responsibility to provide an environment conducive to such good practice. This includes:

- Providing an environment that allows for mutual trust in conversations, discussion and even disagreements;
- Ensure that managerial pressures do not influence the research process;
- Development of a division of labour within research groups must allow for reciprocal criticism and verification of new findings within the group;
- Research group leaders should maintain an awareness of activity within their group and the leadership chain in any group should not become too long;
- Ensuring that commercial pressures do not unduly influence research outcomes and that integrity is maintained;
- Requiring research staff to declare any potential conflicts of interest with regard to their research and ensuring that these are managed within research groups;

³ Drawn from the DFG report and adopted by the EPSRC.

- Introducing adequate induction programmes and training provision for new or inexperienced research staff and for all research students and their supervisors;
- Providing working environments and ensuring work practices meet with Health and Safety requirements as specified by the University.

3 Education of New Researchers

The education and development of new researchers needs special attention. Faculties, Research Institutes and Centres should ensure that responsibility for mentoring new researchers is clear.

- 3.1 Each new researcher should have a more senior researcher primarily responsible for his or her progress and should receive adequate supervision.
- 3.2 The Postgraduate Research Tutor in each faculty will act as a confidential independent source of information and advice for new researchers if they are experiencing difficulties in their immediate research team.
- 3.3 It is important to ensure that students and research assistants are not put under unwarranted pressure to produce results at any cost. This could result from an over emphasis on producing publishable results for future employability for example or to gain additional funding from sponsors.

4 Retention of Primary Data

Primary data produced at the University as the basis for publication should be stored at the University, for a period at least as long as that required by any sponsor that has funded the research.

- 4.1 Storage of primary data is essential for reproducibility, both internally and by external laboratories, and is therefore an indispensable condition of good research. The loss of primary data is common to cases of scientific misconduct and justifies a prima facie assumption of dishonesty or negligence.
- 4.2 Retention of data is also a key to working efficiency. It becomes all the more important where the published results are challenged by others. Data may be stored on space saving techniques, where appropriate (such as disc or CD-ROM) but it is important that data is retained at the University even following relocation of principal investigators to other institutions, irrespective of statutory or professional obligations. (Guidelines are currently under development).
- 4.3 In addition, the maintenance of laboratory notes is increasingly important for the protection of intellectual property (detailed advice on this and booklets on keeping laboratory notes are available from the Intellectual Property Team in the Enterprise Centre).

5 Responsibility for Publications

Authors of scientific publications are always responsible for their content. So-called 'honorary authorships' are not permissible. All authors must be able to identify their specific contribution to a paper.

5.1 Other contributions to the work from which the publication arises, including significant ones such as listed below, are not by themselves regarded as sufficient to justify authorship:

- Responsibility for obtaining the funds for the research;
- The contribution of important materials;
- The training of co-authors in certain methods;
- Involvement in the collection and assembly of data;
- Directing an institution or working unit in which a publication arises.

5.2 Where there are a large number of contributors to a piece of research, it may be advisable for an agreement to clarify the authorship and other rights. In this context, it is also important to note that only the person who reduces the research to text will have copyright in the work (which may then be vested in the University).

6 Responsibility for Integrity of Externally Submitted Research Applications

Principal Investigators and those responsible within Schools and Research Institutes for authorising external applications are responsible for taking all reasonable measures to ensure accuracy of information included in funding applications.

6.1 The University acting through its officers - primarily through those authorised to sign-off external applications such as Deans of Faculties, Assistant Deans for Research and Business Development and the Pro VC for Research and Business Development - also has a responsibility to the ensuring that research misconduct does not occur.

6.2 In this respect, Faculties and Research Institutes should also seek to encourage the practice of internal and/or external peer review as appropriate to the subject content, over and above the signing off of applications by the appropriate director.

6.3 When undertaking external peer review of research proposals or publications academic and research staff should strictly adhere to the guidelines provided by the sponsoring body.

7 Standards in Public Life

Attention should also be draw to the recommendations of the Nolan Committee on Standards in Public Life. The Committee sees higher education as one of the key areas of public life and the seven principles outlined by the committee have relevance to best practice in the conduct of research, namely: selflessness, integrity, objectivity, accountability, openness, honesty and leadership.

Section 2 Dealing with Allegations of Research⁴ Misconduct

Scope

This policy and associated procedures apply to all employees, visiting researchers and fellows working at the time the misconduct is alleged to have occurred within University establishments and teams. Where allegations of misconduct are made by an individual or body external to SHU that individual or body will be made aware of the University's procedure and of the University's expectation that they will comply with its requirements.

1 Introduction

1.1 If a *prima facie* case of research misconduct arises within the University, the matter will be dealt with by the following procedure. This procedure has been informed by the recommendations of:

- The Commission of Professional Self Regulation in Science⁵;
- The Report of the Royal College of Physicians on Fraud and Misconduct in Medical Research;
- The MRC's Policy and Procedure for Inquiry into Allegations of Scientific Misconduct;
- The Scottish Universities' Research Policy Consortium's recommendations in respect of Scientific Integrity in Research;
- EPSRC's Good Practice and Engineering Research;
- The Wellcome Trust Guidelines on Good Research Practice;
- The report on Active Risk Management in Education;
- The Missenden Centre Code of practice for Ethics and Accountability;
- The BBSRC Issues of Public Concern.;
- ESRC guidelines.

1.2 By and large the above recommend a three stage self-regulatory approach, as is adopted below, involving the following stages:

- Screening
- Assessment
- Formal Investigation

1.3 The procedure below also adopts a delegated approach. The procedures will operate independently of the project management and the line management of the researcher(s) allegedly involved.

1.4 Attention is also drawn to the Public Interest Disclosure Act 1998 which states that employees who disclose information on certain matters in good faith will be legally protected from being disciplined, dismissed or victimised by their

⁴ In the context of this policy 'scientific' is taken to cover all epistemological activity, including for example historical research and other such forms of knowledge generation.

⁵ Commissioned by Deutsche Forschungsgemeinschaft (the German Research Association)

employer as a result. Staff who believe here to be a serious case of research misconduct are encouraged to use the following procedure. A general University policy on 'Whistleblowing' is contained in the HRD Managers' Handbook.

2 What is Research Misconduct?

In the context of this procedure, the term 'Research Misconduct' includes the following:

- **Fabrication** – the deliberate invention of data
- **Falsification** – the deliberate and selective rejection of undesired results, the distortion of conclusions or misrepresentation of results of other researchers
- **Plagiarism** – the deliberate presentation of documented words or ideas of another as ones own, without attributions or the making use of ideas in breach of confidentiality associated with peer review or supervision;
- **Deception** – the failure to declare a conflict of personal interest or deliberately misleading statements in pursuit of research funding.
- **Non-compliance** – the wilful failure to comply with the statutory obligations concerning the use of human or animal subjects or of biohazards materials.
- **Facilitating misconduct by collusion or concealment** – failing to challenge or choosing to deliberately ignore unethical research practices amongst colleagues or students.

It does not include honest error or honest difference in methodological approach, research design, interpretations or judgements of data.

3 Confidentiality

An allegation of research misconduct is serious and potentially defamatory, and therefore could be actionable in law. Consequently, for the protection of the *accuser*⁴ and *accused*, all information submitted in relation to an allegation of misconduct will be dealt with confidentially and will only be disclosed to those parties involved in the investigation and judgement of the allegation, or as is necessary to progress the accusation, or as required by law.

4 Stage 1 - Screening

- 4.1 Initial allegations should be made in writing to the appropriate Executive Dean of Faculty or Director of Research Institute, or appropriate line manager in cases where the allegation is against an Executive Dean or Director of a Research Institute ('the Screener'), who shall immediately consider the allegation to determine whether it falls within the scope of this procedure and whether an assessment is warranted. If the allegation is deemed to be frivolous or without substance, the Screener should dismiss the allegations and inform the *accuser* accordingly. The Screener may seek confidential, legal or other expert advice to assist in such a determination.

⁴ Throughout this procedure the terms 'accuser' and 'accused' are used. No usual judicial interpretation is intended by this usage.

- 4.2 The Screener must inform the *accused* of the allegation but shall guarantee the anonymity of the *accuser*. The *accused* shall be given the opportunity to respond. The allegation and the identity of the *accused* should not at this stage be disclosed to anybody else other than as part of the Screener seeking advice in 4.1
- 4.3 If the Screener is not satisfied with the response of the *accused*, he or she shall proceed to the next stage. In this instance the Screener shall immediately arrange for all necessary documentation and material (inc. computer discs etc) to be secured and shall inform the Pro Vice-Chancellor for Research and Business Development ('the PVC') of the matter.
- 4.4 The Screener shall also take any action that is required to ensure compliance with health and safety regulation necessary as a result of the alleged misconduct.

5 Stage 2 Assessment

- 5.1 The purpose of this stage is to determine whether there is a *prima facie* evidence of misconduct, not to reach a final conclusion.
- 5.2 Should the Screener determine that a *prima facie* case of misconduct exists he or she shall inform the PVC who shall then appoint an Assessment Committee consisting of three acknowledged experts, including at least one who is fully familiar with area of research concerned, to advise him/her, under conditions of strict confidence. The precise composition of the Assessment Committee shall be at the discretion of the PVC, possibly including a member who is external to the University.
- 5.3 The *accused* shall be given the opportunity to explain any apparent inconsistencies or irregularities which may have become apparent from the receipt of the allegation. This should take the form of confidential written communication between the Screener and the *accused*. As far as is compatible with proper assessment of the allegation, the identities of the *accuser* and *accused* will not be disclosed to the Assessment Committee.
- 5.4 Normally, the assessment should be completed within a period of no longer than 60 working days and following the provision of a report of the Assessment Committee's conclusion to the *accused*, the *accused* shall respond in writing within 20 working days.
- 5.5 If the Assessment Committee determines that there is not sufficient substance to the allegations to instigate a formal investigation (stage 3), then both the *accuser* and the *accused* shall be informed and the case shall be dismissed.
- 5.6 If a decision is taken to proceed to Stage 3 any funding bodies associated with the research will be informed in confidence.

6 Stage 3 Formal Investigation

- 6.1 The purpose of this stage is to examine and evaluate all relevant facts to determine whether research misconduct has been committed, and if so the responsible person(s) and the seriousness of the misconduct.
- 6.2 Both the *accuser* and *accused* shall be informed of the intention to move to Stage 3, reminded of the need to maintain confidentiality and to cooperate.
- 6.3 The PVC will then appoint a three person committee (some of whom may have been on the Assessment Committee). They will appoint their own chair and shall not have any conflicts of interest. They should have the necessary expertise to examine the evidence, interview the *accused* and any relevant witnesses and conduct the investigation and possibly include a member external to the University. Administrative support will be provided centrally to document the process.
- 6.4 Given the nature of this Investigation Committee, it is important that confidence is maintained to avoid possible defamation and, given the quasi-judicial nature of the procedure, that natural justice is maintained. Advice in this respect may be obtained from the University Secretary (who shall be informed in any case) and others as appropriate.
- 6.5 The PVC will notify the *accused* of the composition of the Investigation Committee and he or she shall have the right to object in writing to any of the persons so appointed. The PVC may then replace the challenged person with a qualified substitute. If the PVC refuses to do so, the reasons for the objection and its overruling shall be part of the investigation report.
- 6.6 The *accused* can elect to be accompanied by one other person. However, the *accused* may not have legal representation without the prior consent of the chair of the Investigation Committee, which will only be granted in exceptional cases.
- 6.7 The Investigation Committee shall endeavour to conduct the investigation as to retain the confidence of both the *accuser* and the *accused*.
- 6.8 Confidential records of all stages of the procedure must be agreed and kept securely.

7 Findings

- 7.1 The Committee will report to the PVC and the Faculty Executive Dean or Research Institute concerned (In cases where an Executive Dean or a Director of a Research Institute is the *accused*, the references in these paragraphs to Executive Dean or Director of Research Institute should be taken to be the appropriate line manager).

7.2 If the allegations of serious scientific misconduct are confirmed, the PVC in consultation with the Executive Dean will decide what action needs to be taken. This might include sanctions which may include one or more of:

- Letter of reprimand
- Withdrawal of funding
- Requiring the withdrawal or correction of pending or published abstracts and papers emanating from the research in question
- Changes to the staffing of the particular project
- Special monitoring of future work

Disciplinary action under the University's Staff Disciplinary Procedures may also be instigated and may give rise to any of the sanctions possible under the Procedures.

7.3 Where the research has been externally funded the funding body will be notified of the outcome. If appropriate, relevant professional bodies will be informed. Funding and professional bodies may also impose sanctions in these circumstances.

7.4 If it is found that misconduct has not occurred but serious research errors have been made, the matter will be dealt with internally within the institution, at the direction of the Executive Dean. Action may be required to correct errors, for example by publication of a retraction, or correction, of data, or information, in the journal where the original work was published. In research involving human participants the appropriate research ethics committees shall be informed.

7.5 If it is found that no misconduct has occurred, steps should be taken to preserve the good reputation of the *accused*, and in any event to protect the *accuser* from any adverse repercussions (save where the allegation has been made maliciously). If the case has received publicity, the researcher subject to investigation shall be offered the opportunity of having an official statement released to the media and the University may wish to comment anyway.

8 Appeal

Any appeal regarding the findings of the Investigation Committee and/or the sanctions proposed shall be made directly to the Vice-Chancellor, within 20 working days of the accused being informed of the outcome. The Vice Chancellor's decision shall be final.

9 Malicious Allegations

Should the Committee of Investigation determine that the allegation(s) is (are) malicious the PVC shall be informed and he or she shall invoke appropriate disciplinary action.

For further information, please contact: Alison Cooper, Secretary to the University Research Ethics Committee, Research Support Office, City Campus. Tel: 4050

January 2004.

RESEARCH FUNDING FROM EXTERNAL SOURCES **(*Research Ethics Policies and Procedures: 3*)**

1 Introduction

- 1.1 The University encourages its staff and students to engage with the external world, to be innovative and risk-taking, and to seek funds from a diverse range of sources.⁵ It is to be expected that, sometimes, researchers will undertake work where both the questions and the answers are controversial and challenge vested interests. On such occasions the University should be vigorous in protecting the integrity of knowledge and its own independence. However, there may be circumstances in which particular funding or collaboration is unethical, imprudent or otherwise against the interests of the University as a corporate body.
- 1.2 It is beyond the scope of this statement to give examples of what may or may not be acceptable. What it aims do is to raise the key issues, outline some broad principles, and identify responsibilities for decision making.

2 Potential Issues

Some of the circumstances where there may be concern can be categorised as follows:

- 1) Sponsors may put pressure on researchers to suppress or alter results which do not further, and indeed may damage, their interests. This may infringe a researcher's intellectual property rights and ultimately their employability.
- 2) The University may be presented with a dilemma by funding bodies themselves which refuse to sponsor institutions in receipt of funds from certain other bodies. One example involved the Cancer Research Campaign and sponsorship by tobacco companies.
- 3) The University itself may decide that the practices of a potential sponsor are so inimical to its own mission and character that it should not accept funding from that source.
- 4) The University may decide that a collaboration would be so damaging to its reputation that it would not be prudent to accept funds.
- 5) A research project may involve collaborating with institutions and organisations in other parts of the world which may not adhere to similar ethical and environmental codes. For example they may not have equal opportunities and disability legislation.

⁷ Sheffield Hallam University Vision and Values Statement, February 1999

3 Principles

- 3.1 The first of the categories listed above is, perhaps, the most straightforward to deal with as such problems should be covered by the contract authorisation process and the policies on safeguarding integrity in research and the ethical conduct of research involving human participation.
- 3.2 The other areas are more difficult and delicate. Decisions should be based on the following broad principles.
- The expectation should be that the University will accept funds from any legal source for sound research where that funding meets the requirements of current financial and contractual policies.
 - In responding to the exclusion policies of sponsors (see 2 above), the University should, where possible, seek to agree a common response and position with other HEIs. It should also take into account the balance of damage to the University and the strength of the ethical argument of the body imposing conditions.
 - Any refusal to accept funds on ethical grounds (see 3 above) should only take place where there is a clear and major conflict of values.
 - Any refusal to accept funds because of potential damage to reputation (see 4 above) should only take place where there is a strong possibility that the damage will be so great that it will seriously undermine a significant part of the University's activities.
- 3.3 With regard to collaborating with institutions and organisations in other parts of the world which may not adhere to similar ethical and environmental codes, it is suggested that collaborating organisations in such circumstances should agree to develop a plan of action that will eventually bring their policies and practices in line with the university policy. (The Missenden Centre Code of Practice for Ethics and Accountability and the Guidelines on Ethical Trading produced by a consortium of trade unions, Oxfam and Marks and Spencer are useful sources of practical advice in this area).

4 Responsibilities

- 4.1 The Research Support Office will be the repository for decisions so that it may inform University enquirers of any relevant precedent.
- 4.2 If a researcher has any doubt as to the acceptability of a particular source, he or she owes a clear duty of care to the University and must seek advice from the relevant Executive Dean of Faculty or Director of Research Institute.
- 4.3 In cases where the difficulties cannot be resolved following 4.1 or 4.2, queries should be referred to the Pro Vice-Chancellor for Research and Business Development. He or she may seek the advice of the University Research Ethics

Committee and may consult with the University Secretary and the Vice Chancellor if appropriate.

Appendix 1 - Guidelines and Codes of Practice

The original SHU Research Ethics Policy was developed using the following documents:

Research on Human Participants

1. Declaration of Helsinki – Recommendations guiding physicians in biomedical research involving human participants (1996)
2. Guidelines for good clinical practice in clinical trials - Medical Research Council (MRC) (1998)
3. MRC Ethics Series
 - The Ethical conduct of research on children (1993)
 - The Ethical conduct of research on the mentally incapacitated (1993)
 - Principles in the assessment and conduct of medical research and publicising results (1995)
 - Responsibility in the use of personal medical information for research (1994)
4. Guidelines on standards for the facilities in which studies on non-patient volunteers are conducted – The Association of the British Pharmaceutical Industry (1989)
5. Code of conduct, ethical principles and guidelines – The British Psychological Society (1995)

Research on Animals

6. Animals (Scientific Procedures) Act 1986
 - Code of Practice for the Humane Killing of Animals under Schedule 1 (1997)
 - Application form for a project licence and notes for completion of application form (1991)
 - Application form for a personal licence and notes for completion of application form (1994)
7. MRC Ethics Series: Responsibility in the Use of Animals in Medical Research (1993)

Scientific Integrity

8. Safeguarding Good Scientific Practice – A joint statement by the Director General of the Research Councils and Chief Executives of the UK Research Councils (1998)
9. Good Practice in Scientific and Engineering Research – EPSRC (1999)
10. Fraud and Misconduct in Medical Research – Causes, investigation and prevention – Royal College of Physicians (1991)
11. MRC Ethics Series: Policies and Procedures for Inquiring into Allegations of Scientific Misconduct (1997)
12. University Research in Scotland – Developing a Policy Framework (chapter 8 Scientific Integrity in Research, Chapter 9 Publication and Research Ethics, Chapter 10 Academic Freedom and Research) – The Scottish Universities Research Policy Consortium (1997)

The following documents have been taken into consideration for the new policy:

ARMED – Active Risk Management in Education - Research Misconduct

Association for International Cancer Research Agreement Relating to a Grant Offered – also applies to Cancer Research UK Dated 22nd March 2002

Association of Medical Research Charities - Various guidelines including 'Good Research Practice'

Biotechnology and Biological Science Research Council (BBSRC) Statement on Safeguarding Good scientific Practice, (BBSRC website July 2003)

Department of Health - Research Governance Framework

EPSRC– Engineering and Physical Science Research Council - A Guide to Good Practice in Science and Engineering Research

European Commission - Research Ethics and Framework 6 (Science and Society)

European Science Foundation - Policy Briefing Good Research Practice and Clinical Trials

The Missenden Centre Code of Practice for Ethics and Accountability

MRC – Medical Research Council - Ethics and good Practice and a series of guidelines

OST – Office of Science and Technology - Safeguarding Good Scientific Practice

Wellcome Trust, Guidelines on Good Research Practice, 15th February 2002

And Statement on Handling Allegations of Research Misconduct, 11th January 2002

World Medical Association Declaration of Helsinki – revised version October 2000.

A copy of the Kings College London Manual for Research Ethics Committees 6th Edition 2003 is available for consultation via the Research Support Office.