THE UNIVERSITY OF SHEFFIELD

RESEARCH ETHICS APPROVAL PROCEDURE

1 INTRODUCTION

The University's approach to research ethics requires that all research involving human participants, personal data, or human tissue should be reviewed, and research ethics approval obtained, before data gathering commences.

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

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

In addition, all individuals who, although they are not members of the University, conduct, or contribute to, research activities involving human participants, personal data or human tissue that take place within University premises and facilities are expected to ensure that ethics approval for their research project(s) is obtained via an appropriate route (e.g. via the ethical review procedure at their own University or organisation).

The University's definition of research is 'a process of investigation leading to new insights, effectively shared'; the full details are outlined in the General Principles and Statements section of this Policy. The definition of a participant is outlined in Research Ethics Policy Note no. 1.

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

2 ROUTES FOR OBTAINING ETHICS APPROVAL

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

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

In addition, there is a legal requirement for research involving adults lacking in mental capacity to be reviewed by a recognised Appropriate Body under the Mental Capacity Act 2005. Appropriate Bodies include some NHS research ethics committees and the Social Care Research Ethics Committee (see section 2.3). For further information, refer to Research Ethics Policy Note no. 5 and the Specialist Research Ethics Guidance Paper entitled 'Research involving adult participants who lack the capacity to consent'.

2.1 The University Ethics Review Procedure (University Procedure)

This applies to research which:

- comes under the broad definition of 'a process of investigation leading to new insights, effectively shared';
- is led by the University of Sheffield;
- does not require ethical review via an NHS Research Ethics Committee or the Social Care Research Ethics Committee; and
- is undertaken in the United Kingdom (or abroad, unless there is an appropriate alternative – see section 2.4 below).

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

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

Review by an NHS REC forms part of the Heath Research Authority's HRA Approval process. In general, review by an NHS REC will be required for research that involves participants identified from, or because of, their status as patients of the NHS or other Department of Health Services, and/or the relatives of such patients. There are also specific types of health care research that will require review by an NHS REC (e.g. a clinical trial of an Investigational Medicinal Product and research involving the collection of human tissue). Research involving only the premises and/or staff of the NHS or other Department of Health services does not require review by an NHS REC. Researchers should refer to the HRA's ethics decision tool for full details:

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

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

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

2.3 The national Social Care Research Ethics Committee

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

2.4 The Alternative Ethics Review Procedure

This applies to:

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

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

2.5 The Administrative Research Ethics Review Procedure

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

3 THE UNIVERSITY ETHICS REVIEW PROCEDURE (UNIVERSITY PROCEDURE)

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

The University Procedure is based on the following guiding standards:

- Quality: competent and consistent decision-making by ethics reviewers within, and across, departments should be enabled and encouraged.
- Effectiveness: the dignity, rights, safety and well-being of participants and researchers must be protected.
- Devolution: applications should be reviewed at department level, enabling researchers to 'own' their own research ethics, thereby raising awareness and allowing research to be reviewed by those with close knowledge of the particular ethical challenges raised by their departments' research activities.
- Flexibility: departments should, within the minimum requirements set by the University Research Ethics Committee (UREC), be able to tailor the procedure to fit their particular needs in a number of ways, such as enabling ethics reviewers to undertake the reviewing process individually via the online ethics system, or at a face-to-face committee meeting; being able to invite additional ethics reviewers to be involved where an application presents particular risks or challenges; or by creating discipline-specific guidance.
- Ease of application: the procedure is designed to be as simple and prompt as possible, while maintaining high standards. For example, when successive cohorts of undergraduate or postgraduate-taught students are required to undertake sufficiently similar research projects, a single 'generic' research ethics application can be submitted.
- Efficiency: on average, departments should provide a decision on an ethics application within 10 working days.

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

Although ethics approval is required before any data collection involving human participants commences, applicants are expected to consider the ethical implications of their research at all stages of the project. Even the most well thought-out project may come across unexpected ethical challenges after approval has been obtained, and researchers should constantly reflect on the ethics of their research. If changes are made to the project after approval has been obtained, it may be necessary to obtain re-approval in certain circumstances, which are explained in Section 3.1.8 of this Policy document.

The University has an online Ethics Application System which facilitates the ethics review process, and all academic and professional services departments are expected to use this for the processing of ethics applications, with the exception of Student Services which has a tailored paper-based process with additional steps incorporated (NB. specific details relating to administrative research are provided in Research Ethics Policy Note no. 7). However, since individual departments have some flexibility in how they operate the University Procedure, applicants are encouraged to refer to their own department for details before applying. The following section outlines the minimum requirements set by the UREC, within which departments must operate the procedure.

If changes need to be made to the project after approval has been obtained, refer to Section 3.1.8 of this Policy document.

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

3.1 The University Procedure in practice

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

Each academic department administers the University Procedure and grants ethics approval for research undertaken by its own researchers. Each department has a designated Ethics Administrator who is responsible for the administration of the procedure on a day-to-day basis, and a pool of ethics reviewers who conduct the ethical review of research projects submitted to the department. Any University member of staff may become an ethics reviewer (with the approval of their Head of Department). Departments should ensure that staff appointed as ethics reviewers receive appropriate training and/or guidance to help them fulfil this role effectively (e.g. attending UREC training events, shadowing a more experienced ethics reviewer, referring them to relevant resources/websites).

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

members of the Ethics Review Panel or Research Committee should have a conflict of interest with the project in question.

Each department also has its own designated Principal Ethics Contact, who will normally communicate any changes in, or information relating to, the University Procedure to staff and students in the department. This person may also be the Ethics Administrator. The names of Ethics Administrators and Principal Ethics Contacts can be found at:
https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/index

Sometimes, due to the requirements of a funding body or any other external body the cooperation of which is necessary for the research to proceed, lay input into ethical scrutiny will be required. In such cases, ethical scrutiny of research projects will be undertaken by a sub-committee of the University Research Ethics Committee (see section 3.1.5 for more details).

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

3.1.2 How is a research project submitted for ethical review?
The researcher completes and submits the online ethics application form (the Ethics Application System is accessed through 'My Services', and further details on how to submit an application can be found here:
https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/educationresources/onlinesystem
The application form should be accompanied by any relevant documentation. For example, if it is intended to use an information sheet, covering letter or written script to inform prospective participants about the proposed research, or if a consent form will be used to record participants' consent to participation in the research, these should form part of the application. Applicants should also provide further information such as the interview schedules, questionnaires or other research tools that they plan to use, if these are available at the time of review; departments are encouraged to adopt this as best practice, with recognition of the fact that it may not always be possible. Ethics reviewers may ask for subsequent sight of these, if they are not available at the time of applying.

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

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

3.1.3.1 Distinct research projects: Where an undergraduate or postgraduate-taught student requires ethics approval for an individual research project that is distinct from any other

student research, the supervisor is responsible for classifying the research as either 'low risk' or 'potentially high risk' (on risk assessment, see Section 3.1.4). A reduced number of ethics reviewers is required to review such projects, dependent on the risk level posed (for full details see Section 3.1.5).

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

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

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

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

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

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

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

Where a research activity that has been granted generic research ethics approval is repeated with different cohorts of students on a year-on-year basis, the Ethics Administrator and the academic staff member responsible for the activity should *review* the approval every year, to ensure that the activity in question has not changed sufficiently to render the original approval inapplicable. This annual review process, and the decision reached, should be documented. If

there has been significant change, a new generic ethics application should be submitted. If there has not, a generic ethics approval should, anyway, be *renewed* every five years, i.e. a new generic ethics application should be submitted for review.

3.1.4 Assessing ethical risk

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

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

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

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

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

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

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

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

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

Potentially highly sensitive topics include:

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

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

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

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

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

- For staff applications, this will be the departmental Ethics Administrator, who will then assign appropriate reviewers as per the minimum requirements set out below;
- For students at all levels, this will initially be the supervisor named in the application, enabling them to check that they are satisfied that the application is of an appropriate standard to be submitted for ethical review. Following the supervisor check, applications from postgraduate research students will be submitted to the departmental Ethics Administrator, who will assign appropriate reviewers; for undergraduate and postgraduate taught student applications, the supervisor will be asked to assess whether the project is low risk, or potentially high risk. Low risk applications may be reviewed by the supervisor themselves, and potentially high risk

applications will be sent to the departmental Ethics Administrator to appoint appropriate reviewers, as per the minimum requirements set out below.

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

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

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

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

- A minimum of three ethics reviewers is required to undertake a research ethics review of either a staff-led, or a supervised postgraduate, application. None of the ethics reviewers may have any conflict of interest with the application.
- A minimum of two ethics reviewers is required to undertake an ethics review of a potentially 'high risk' research application from a supervised postgraduate-taught or undergraduate student. At least one of the ethics reviewers must not have any conflict of interest with the application. However, one of the ethics reviewers may be the student's supervisor, at the discretion of the academic department concerned.
- Only one ethics reviewer is required to review 'low risk' research applications from supervised postgraduate-taught or undergraduate students. This ethics reviewer may be the student's supervisor. However, academic departments have the discretion to require that more than one ethics reviewer reviews low risk applications from such students, and/or that an ethics reviewer in such a case cannot be the supervisor.
- A minimum of three ethics reviewers must review generic research ethics applications, as defined in Section 3.1.3.2.
- If there is a significant, fundamental difference of opinion between ethics reviewers about the ethics of a proposed piece of research, then a group of at least three ethics reviewers (e.g. an Ethics Review Panel or Research Committee), none of whom should have a conflict of interest with respect to the project in question, must review the application.
- If members of the Ethics Review Panel, or equivalent, cannot reach a consensus then the UREC will undertake an ethics review of the application. If the matter is urgent this may be done through Chair's action, in consultation with other committee members.
- If an application is not approved as a result of an initial ethics review, the applicant may appeal against the initial decision by contacting the department's Ethics Administrator,

who should arrange for the Ethics Review Panel or equivalent to review the application. Such an appeal can only be made through the department to which the initial application was submitted. If an applicant wishes to appeal against the decision of an Ethics Review Panel or equivalent, then s/he should contact the Minute Secretary to the UREC, who will arrange for the UREC to review the application. If the matter is urgent, this may be arranged through Chair's action, in consultation with other committee members. The UREC's decision is final.

- Where external ('lay') input to the ethics review process is necessary, due to the requirements of a funding body or any other external body the cooperation of which is necessary for the research to proceed, ethical scrutiny of research projects will be undertaken by a sub-committee of the University Research Ethics Committee, comprising two ethics reviewers from the project's department of origin, one external member from the UREC, and additional members of the UREC as required on a case-by-case basis in order to meet the requirements of the external body. In such cases, the departmental Ethics Administrator should liaise with the UREC's Minute Secretary to identify appropriate ethics reviewers from the UREC.

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

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

- *Approval*: the project can go ahead with no changes.
- *Approval with suggested amendments*: the project can go ahead but the applicant may wish to consider suggestions made by the reviewer(s); these, however, are optional.
- *Approval with compulsory changes*: the project cannot go ahead until required changes have been made; the reviewer(s) must see the revised version of the application and subsequently approve it. (Suggested amendments can also be made alongside the compulsory changes)
- *Rejection (not approved)*: the project cannot proceed, for reasons that should be clearly specified by the reviewer(s).
- *No decision*: this indicates a contentious project, which will need to be reviewed by an Ethics Review Panel, or equivalent (and if no agreement is reached, by the UREC).

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

Ethics reviewers have, with the applicant(s), responsibility for the quality of the ethics application. Where they feel that the applicant has not included sufficient detail for the reviewer to make an informed judgement, they should ask that the applicant clarifies or expands on the information that has been provided before a decision can be made.

Once a final decision has been made, an email notification will be sent to the applicant and a printable letter of approval will be available through the Ethics Application System. The reviewers will be able to access the application as well in order to see the final decision and the comments provided to the applicant.

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

A relatively straightforward ethics review should ideally take approximately ten working days (the exact timing will depend on the academic department, and circumstances). However,

delays can occur if a research ethics application form is not fully completed, if the ethics reviewers request more information, if an application is judged contentious, or if the applicant appeals against the ethics decision.
Ethics Administrators should make appropriate efforts to ensure that the reviewers they appoint will be available to complete the review within the allotted timeframe (e.g. by checking colleague's calendars). Appointed ethics reviewers should make every effort to complete reviews within the deadline set by the Ethics Administrator, in order to avoid unnecessary delays to colleagues' and students' research. If a reviewer is unable to perform a review within the defined period (e.g. due to a period away from the University, or sickness), they should alert the Ethics Administrator promptly so that alternative arrangements can be made.

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

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

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

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

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

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

3.1.10 When is research ethics approval NOT required?

Ethics approval is not required in the following situations:

- The project is not research, under the definition provided in the 'General Principles and Statements' section of this Policy.
- The project does not involve human participants, either directly (e.g. through use of interviews, questionnaires) or indirectly (e.g. through provision of, or access to, personal data or tissue material). This includes:
    - A project which will only use publicly available anonymised data, such as census, population or other official statistical data;
    - A project which will only use existing clinical or research data that has been robustly anonymised such that it no longer constitutes personal data (i.e. the original providers of the data cannot be identified by the Data Controller using either the dataset itself, or any other dataset that is either held by, or is likely to come into the possession of, the Data Controller). In such cases, the researcher should carefully consider the new research purpose in terms of whether it is likely to cause offence to those who originally provided the data (or other relevant groups of individuals), and should be confident that this would not be likely. Researchers are encouraged to use the self-declaration process available via the online Ethics Application System, to ensure that they have addressed all relevant considerations in using existing data as part of their project, and to ensure that this process has been appropriately documented.

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

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

3.1.11 Procedure to be followed in the event of concerns arising about whether a research proposal or ongoing research activity complies with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue

Should, for whatever reasons, concerns arise about whether a research proposal or ongoing research activity complies with the University's Ethics Policy Governing Research Involving Human Participants, Personal Data and Human Tissue, the Chair of the UREC should contact the Head of the Department concerned, as the person ultimately responsible for the implementation and observance of the Policy within that Department, requesting that the research activity in question, or the approval process with respect to the proposal in question, be suspended in order to allow an investigation of the case. The UREC and the Department in question should carry out any such investigation collaboratively and as a matter of urgency. In the case of students who have not obtained the appropriate ethics approval for their project, the Senate-approved '*Procedure for dealing with students who have not obtained research ethics approval'* should be followed (see section 3.1.12 below).

Should a member of staff or a student have concerns about whether a particular project is being managed ethically, they should in the first instance report this to their Head of Department and the issue should be investigated informally. If the concerns are substantiated, the Chair of the University Research Ethics Committee should be informed and the University's Policy on Investigating and Responding to Allegations of Research Misconduct, or another appropriate University procedure, may be activated (further details are set out in the University's Good Research & Innovation Practices policy).

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

General University Regulation 10 states that:

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

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

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

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

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

4 THE ALTERNATIVE ETHICS REVIEW PROCEDURE

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

4.1 Research conducted overseas

Research that will take place in another country and will involve human participants from that country may require ethics approval via an appropriate ethics review procedure in that country. A review and assessment of how local approval is obtained is an essential part of the ethical review process. Where such a procedure exists, it may *not* be necessary for the researcher to seek ethics approval via the University of Sheffield's Ethics Review Procedure, providing that the overseas procedure is judged to be sufficiently robust by the UREC (refer to Section 4.2.1 for details of the relevant assessment process).

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

Some departments may prefer to adopt a 'belt-and-braces' approach, in which research ethics review is always undertaken via the University Procedure, regardless of procedures

elsewhere. This ensures that departmental, and University, ethical oversight is assured. It is important, therefore, that researchers check the policy of their own department with respect to this issue by contacting their Ethics Administrator or Principal Ethics Contact.

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

4.2 Research led by another United Kingdom university

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

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

A list of institutions with ethics review procedures that have already been judged to be sufficiently robust is provided at:
https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/approval-procedure/alternative
Where ethics approval will be sought via the ethics review procedure of one of the institutions listed, no further information will be required about the robustness of the procedure. However, following the ethics decision, the researcher must create a new ethics application in the online Ethics Application System, selecting the option that confirms that the research is either taking place outside the UK, or is being led by another UK institution, and then follow the process for submitting copies of (1) the research ethics application form and (2) a letter from the institution's ethics body confirming its ethics decision with respect to the project.

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

- A copy, preferably electronic, of the institution's research ethics application form, in order that this can be compared with the University of Sheffield's research ethics application form, to clarify whether or not the institution's ethics reviewers are reviewing applications against the same criteria.
- Information on the ethics reviewers, if known; in particular, the number of ethics reviewers and details of their employers. If the institution's ethics review procedure has a website in English then the details should be provided.

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

If the procedure is deemed to be sufficiently robust, the researcher should then submit the project for ethical review via the approved procedure in the other institution. Following the ethics decision, the researcher must create a new ethics application in the online Ethics Application System, selecting the option that confirms that the research is either taking place outside the UK, or is being led by another UK institution, and then follow the process for

submitting copies of (1) the research ethics application form and (2) a letter from the institution's ethics body confirming its ethics decision with respect to the project.