

Notes for Guidance

1. Membership

The Research Ethics Committee was established by the Council on the recommendation of the Senate. Its current membership is:

Eight members appointed by the Senate

Dr J. Wright (Chair)
Professor S.C. Todd (Deputy Chair)
Dr P.J. Almond
Dr J. Burchardt
Dr R. Everitt
Professor M.A. Gosney
Dr A.K. Ho
Professor J.A. Lovegrove
Mr N. Spinks

Up to two members appointed by the Council at least one of whom is to be drawn from outside its own membership

Dr G.P. Botting
Mr D. Carpenter

Members appointed by the Research Ethics Committee

Mr J. Crompton
Dr T. Lincoln
Dr A. Penn

A representative of the Students' Union

Vice President Academic Affairs (RUSU)

The Committee may co-opt additional members from time to time.

2. Terms of reference

The terms of reference of the Committee are:

- (a) to assess the ethical propriety of all research using human subjects, human samples (however obtained) or human personal data to be undertaken in the University, or under the auspices of the University, however funded;
- (b) to have discretion on behalf of the University and in the light of ethical considerations to require such modifications as it may think fit and, if necessary, not to allow the research to proceed;

- (c) to offer advice to Heads of School and investigators on the ethical implications of proposed research and to encourage high standards of ethical behaviour in University research on human beings;
- (d) to monitor at its discretion the progress of research projects submitted to it by means of reports or in other ways and, if necessary, to suspend or terminate such research on ethical grounds.

The Committee's operating procedures are set out in Annex A.

3. Scope

- (a) Precise definitions are not possible but the following areas of research come within the terms of reference of the Committee:
 - (i) those involving procedures of an invasive kind, e.g. the taking of tissue samples, the administration of substances or other medical or quasi-medical procedures;
 - (ii) testing procedures such as food acceptability trials, taste panels etc;
 - (iii) psychological, social science and humanities research involving human participants, including questionnaires, surveys, focus groups and other interview techniques;
 - (iv) educational research;
 - (v) research involving human data or records. Ethical concerns are strongest where these data are gathered directly from the subject and then ethical approval is usually required. Where records are in the public domain, or where the subject is deceased, ethical considerations may still be relevant but such research does not normally require ethical approval;
 - (vi) research using personal information or samples stored from previous research (either initially or when a proposal is revised);
 - (vii) the use of biological samples that are anonymised or that consist of surplus tissue from routine operations.
- (b) Investigators should be aware that any research which constitutes, or could be interpreted as constituting, an encroachment on personal privacy requires careful ethical consideration;
- (c) Investigators must be aware of the provisions of the Human Tissue Act 2004 and of the Mental Capacity Act 2005. Further information on both these Acts and their implications for research ethics issues can be found on the Research Ethics website homepage at:

<http://www.reading.ac.uk/internal/res/ResearchEthics/reas-REethicshomepage.aspx>
- (d) The Committee is happy to consider the ethical dimensions of projects which, while they may not come within a strict interpretation of the

terms of reference, raise issues or use material of a kind which may be viewed with scepticism in a non-academic context.

4. Procedures

- (a) Heads of School are responsible for having procedures in place within their School which identify and review all projects that might fall within the Committee's terms of reference. All proposals (including those which may also have to be considered by another body, for example by a National Health Service Local Research Ethics Committee) must be submitted to the Committee unless
 - (i) It is clear beyond reasonable doubt that they do not fall within the Committee's terms of reference, or
 - (ii) a Head of School or authorised Head of Department wishes to operate the exception procedure which is allowed in the case of projects which fall within the categories set out in section 6 below.
- (b) Heads of School and investigators are responsible for submitting proposed projects and should be aware of the seriousness of their position if they proceed without reference to the Committee where this is required.
- (c) The Committee's procedures are designed to avoid undue delay or inconvenience, and to allow non contentious proposals to be dealt with speedily. In most cases decisions are reached by a sub-group and are subsequently reported to the Committee. It should be recognised that, in most cases, the process of consideration can take four weeks, possibly longer. Proposers for whom this timescale seems likely to present particular problems are invited to communicate direct with the Chair. Proposals that need major revision may require a further three weeks before a decision can be reached. For more complex cases, and for all cases where the Committee is considering disallowing or substantially modifying a project, the Head of School and/or investigator may ask to discuss the project at a meeting with the Committee.
- (d) A decision by the Committee to allow a project is not an expert assessment of the research or of the possible dangers or risks involved nor does it detract in any way from the ultimate responsibility which Heads of School (or authorised Heads of Department) and investigators must themselves have for all research which they carry out and for its effects on human subjects. The Committee addresses itself to ethical matters and is dependent upon the information supplied by the Head of School (or authorised Head of Department) and the investigator.
- (e) The decisions of the Committee are binding on Heads of School (or authorised Head of Department) and investigators but there is a right of appeal to the Strategy and Finance Committee.
- (f) The Committee will monitor the progress of projects to which it has previously given agreement to proceed, one year after such agreement. A brief report will be required from the Project Investigator indicating:
 - (i) whether the project is still continuing;

- (ii) whether any ethical issues have arisen in the course of the year relating to the project; and
- (iii) whether there have been any changes to the project methodology or its operation.

Where projects are still continuing one year after agreement to proceed has been given, the Committee will monitor the progress of the project on an annual basis until its completion.

5. Submissions to the Committee

- (a) Submissions are the responsibility of the Head of School (or authorised Head of Department) and the investigator. The most common reason for delays in considering proposals is the receipt of ill-prepared submissions, and this can cause serious problems, particularly when deadlines are close.

The Chair of the Committee is always willing to visit Schools, or to arrange for an appropriate member of the Committee to do so, in order to meet researchers to discuss with them the Committee's procedures and the preparation of submissions.

- (b) The Committee requests that all pages submitted are numbered, and that submissions are received both electronically and in hard copy. Submissions do not have to be in a standard format, but the following must be submitted:
 - (i) A Project Submission Form (Annex B) which must be completed in full and signed by the investigator and the Head of School (or authorised Head of Department). If the project is to be undertaken by a student, the Investigator should be the student's tutor or supervisor, and the form must also be signed by the student.
 - (ii) An Information Sheet and Consent Form, which may be a single document. An Outline Consent Form, which is given only as a guide but will invariably need to be adapted to take account of particular circumstances, is shown in Annex C. Projects which may generate information about the health of a participant should request the participant's date of birth on the Consent Form, in order that GPs can identify their patients if contacted.
 - (iii) For research involving an external sponsor, a statement as to whether an indemnity is appropriate and if so, whether one has been sought or offered.
 - (iv) Further information which is relevant to the Committee (see section 5 (f) below). The Committee will accept a completed NHS REC application form for this purpose.
- (c) The Information Sheet must be on headed notepaper and include a contact name and telephone number. If any of the project investigators are students, this information must be included and their name provided. It must be written in language that is appropriate to the subjects and can be easily understood by them. It must include a summary of the research to be undertaken and its purposes together with a full and clear account

of what will be required of the subject. Serious consideration should be given to consent procedures for minors even though consent will have to be sought from parents, guardians or other responsible adults.

- (d) The following points will need to be covered in the Information Sheet:
 - (i) How the participants are being selected;
 - (ii) The arrangements for informing each participant's General Practitioner, if necessary;
 - (iii) The arrangements for expenses and other payments, if any, to be made to the participants;
 - (iv) The arrangements to allow participants to withdraw at any stage if they so wish;
 - (v) The arrangements to ensure the confidentiality of any material collected during the project, and arrangements for its storage and eventual disposal;
 - (vi) The arrangements for publishing the research results and, if confidentiality might be affected, for obtaining written consent for this;
 - (vii) The arrangements for providing subjects if they so wish with the research results;
 - (viii) A standard statement, indicating the process of ethical review at the University undergone by the project, as follows:

‘This project has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct’.

Should the project have been subject to other similar procedures (such as NHS ethical review), then this should also be indicated.

A copy of the Information Sheet/Consent Form must be provided for retention by each participant.
- (e) Completed Consent Forms must be retained by the relevant School for a minimum period of five years from the date at which the project is completed. The Chair may audit the storage of consent forms from time to time.
- (f) The following list includes further information which should also be supplied to the Committee. It is not an exhaustive list, but gives an indication of other matters which may be relevant:
 - (i) Where invasive procedures are proposed an account of alternative methods that have been considered but discounted.

- (ii) The method of selection of the subjects, and of ensuring that the number of subjects is appropriate to the research proposed. The details of any recruitment process should be provided along with the intended text of recruitment material in the precise format in which it is to appear. If the exclusion criteria includes participants who are pregnant or lactating, the Committee asks that you use its standard wording:
- “Females who are pregnant, lactating, or if of reproductive age and not using a reliable form of contraception (including abstinence) will be excluded.”
- (iii) Safeguards to ensure that subjects are able to give free and informed consent, particularly:
- those who are under 16 years old;
 - those who have learning difficulties;
 - those whose capacity to consent may be impaired within the meaning of the Mental Capacity Act 2005 (projects involving such subjects will also need to be submitted for consideration to an NHS Research Ethics Committee);
 - those who are in a special relationship to the Investigator (eg as employee or student).
- (iv) Procedures to safeguard the mental and physical wellbeing of subjects and to identify any who might be at special risk (eg because of illness or because they are receiving medication).
- (v) The status of any drugs or medicines involved (eg whether they are available only on prescription or are controlled under the Misuse of Drugs Act 1971) and the pharmacological and toxicological data available. Where foodstuffs and other substances are used with a view to testing their effects on the health or well-being of subjects it will be necessary to supply similar information as for drugs and medicines.
- (vi) In cases where it is proposed to take blood samples, confirmation that procedures attached as Annex D will be adopted and the Information Sheet and Consent Form attached as Annex D/1 supplied to subjects.
- (vii) The University has professional indemnity insurance in place which covers most research projects. Arrangements regarding ‘no-fault’ compensation may be required in appropriate cases. (If this is not available from an external sponsor it will fall to the School to meet the costs of the necessary insurance cover). It may be appropriate to include a line on the Information Sheet to detail that “The University has the appropriate insurances in place. Full details are available on request”.
- (viii) Where appropriate, a statement to the effect that the results of the investigation are to contribute to the attainment of a qualification of this or any other University. In such cases, the students involved must be named on the Information Sheet.
- (ix) Arrangements for the Investigator to review the research and identify and report to the Committee on any ethical problems or

risks which were not at first apparent.

6. Exceptions

- (a) In order to reduce the work of colleagues and of members of the Committee a Head of School (or authorised Head of Department) may operate an exception to the arrangements above to apply to all projects which, in the opinion of the Head of School (or authorised Head of Department):
 - (i) do not involve participants who are patients or clients of the health or social services (unless such participation is purely for the purposes of audit);
 - (ii) do not involve subjects whose capacity to give free and informed consent may be impaired within the meaning of the Mental Capacity Act 2005;
 - (iii) do not involve questions that might reasonably be considered to be impertinent or likely to cause distress to any of the participants;
 - (iv) do not involve any element of risk to the researchers or participants;
 - (v) do not involve subjects in a special relationship with the investigator.

The Head of School (or authorised Head of Department) is authorised to agree that such projects be allowed.

Judgments under 6 a(i) above can be particularly difficult and guidelines for Heads of School (or authorised Heads of Departments) are provided in Annex E.

Please note, that whilst the Exceptions procedure also applies to research that is externally funded, researchers and Heads of Schools should be careful to check the ethical regulations of the funding body. Some bodies may require that the project is reviewed by the University Research Ethics Committee rather than a devolved committee. If this is the case, then the project should be submitted to the University Committee in the normal way. Depending on the funding body, Schools/Departments who do not have an ethics review group may still be required to submit externally funded research projects to the University Research Ethics Committee.

- (b) Projects which involve the collection of blood or relevant materials from human subjects as a general source of biological materials (e.g. blood cells or blood proteins) may also be authorised by Heads of School (or authorised Heads of Department) under the exception procedure provided the conditions set out in Annex D are satisfied;
- (c) If a project is not submitted to the Committee, the Head of School (or authorised Head of Department) must be satisfied that the project conforms with the guidelines in section 5 above and in particular that in each case:

- (i) The subject and/or parent receives an Information Sheet explaining the purposes of the project, how they have been selected as potential participants and a full and clear account of what will be asked of them;
- (ii) The subject and/or parent is invited to sign a Consent Form;
- (iii) Copies of the Information Sheet and Consent Form are provided for retention by the subject/parent;
- (iv) The Information Sheet and Consent Form include the name and designation of a member of staff with responsibility for the project together with a contact address or telephone number. If any of the project investigators are students, this information must be included and their name provided;
- (v) A standard statement be included on the Information Sheet/Consent Form, indicating the process of ethical review at the University undergone by the project, as follows:

‘This project has been subject to ethical review, according to the procedures specified by the University Research Ethics Committee, and has been given a favourable ethical opinion for conduct’.
- (d) The Head of School (or authorised Head of Department) should be satisfied that the Information Sheet meets the requirements of paragraph 5(d) above;
- (e) Heads of School (or authorised Heads of Department) are required to monitor the progress of projects agreed under the exceptions procedures, through an equivalent process to that detailed in 4(f);
- (f) Heads of School (or authorised Heads of Department) will be asked to provide an annual report to the Committee, listing the projects which have been considered under these arrangements and any concerns which have arisen as a result of the monitoring procedure detailed in 6(f) above. They should keep records of all projects for inspection by the Committee if required.

Further copies of this guidance may be obtained from:

Dr Mike Proven
 Co-ordinator for Quality Assurance in Research
 Room 217
 Whiteknights House
 Email: m.j.proven@reading.ac.uk

Research Ethics Committee Operating Procedures

Appointments to the Research Ethics Committee

In addition to the members of the Research Committee who are appointed by the Council and by the Senate, the Committee may, from time to time, appoint additional members for appropriate reasons. Such appointments shall be reported to the Senate.

Meetings of the Research Ethics Committee

Annual Plenary Meeting

The Research Ethics Committee holds one Plenary Meeting in each academic year in the Autumn Term, to which all members are invited. At that meeting, the Committee shall consider the following standard agenda items, in addition to any other items which the Chair of the Committee or its members wishes to raise:

- (i) Membership and Terms of Reference of the Committee;
- (ii) A Review of the Committee's operation and procedures, including its *Notes for Guidance*;
- (iii) A draft Annual Report relating to the previous academic year, which includes a list of the projects which the Sub-Groups of the Committee have allowed to proceed, for approval and subsequent submission to the Senate;
- (iv) An Annual Review of the Projects that Heads of School or University Department agreed be allowed in the previous academic year under the Committee's Exceptions procedure.

The Annual Plenary Meeting shall be quorate if seven members of the Committee are present, including at least four of the members of the Committee appointed by the Senate.

Voting at Meetings

Decisions at both the Annual Plenary and the Sub-Group meetings shall normally be reached by consensus amongst the members present. Should it be necessary to hold a vote on a particular issue:

- (i) all members shall have equal voting rights; and
- (ii) the vote shall be decided by a majority decision. In the event of a tie, the Chair has the casting vote

Sub-Group Meetings

The Research Ethics Committee delegates consideration of project submissions to its Sub-Groups which meet on eleven occasions in each academic year. Dates of meetings and submission deadlines are published on the Committee's webpage at <http://www.reading.ac.uk/internal/res/ResearchEthics/reas-REcommittee deadlines.aspx>

Membership of the Sub-Groups shall be

- The Chair of the Research Ethics Committee
A University member of the Research Ethics Committee
- A medically-qualified member of the Research Ethics Committee (who may also be the Chair)
- A lay member of the Research Ethics Committee drawn from among those appointed by the Committee

The Secretary to the Research Ethics Committee shall be in attendance.

In addition to consideration by its members, as listed above, the Sub-Group shall also seek the views of a further University member of the Research Ethics Committee on each project, which shall be passed to the Chair of the Committee before the Sub-Group meets.

Sub-Group Meetings shall be deemed to be quorate if the views of the Chair, the Medical member (who may also be the Chair), the Lay member and one other member of the Committee have been obtained on all projects under consideration.

Consideration of Project Submissions by the Research Ethics Committee

Project Submissions shall be considered by the Sub-Groups of the Research Ethics Committee and those projects allowed to proceed shall be listed in the Annual Report of the Committee to the Senate.

Project Submissions shall also be copied for information to:

- (a) The University's Insurance Officer
- (b) The Co-ordinator for Quality Assurance in Research, in the circumstances that the project is either funded by an external body or involves patients of the NHS
- (c) A representative of Health and Safety Services (*pro tem* the Biological and Scientific Safety Adviser)

Arrangements relating to Chair's Action

Project Submissions may be considered under Chair's Action in exceptional circumstances.

Research Ethics Committee



Project Submission Form

Note All sections of this form should be completed.
Please continue on separate sheets if necessary.

Principal Investigator:

School:

Email:

Title of Project:

Proposed starting date:

Brief description of Project:

I confirm that to the best of my knowledge I have made known all information relevant to the Research Ethics Committee and I undertake to inform the Committee of any such information which subsequently becomes available whether before or after the research has begun.

I confirm that I have given due consideration to equality and diversity in the management, design and conduct of the research project.

I confirm that if this project is an interventional study, a list of names and contact details of the subjects in this project will be compiled and that this, together with a copy of the Consent Form, will be retained within the School for a minimum of five years after the date that the project is completed.

Signed:

..... Date:
(Investigator)

..... Date:
(Head of School or
authorised Head of Department)

..... Date:
(Student -where applicable)

Checklist

1. This form is signed by my Head of School (or authorised Head of Department) ☐
2. The Consent form includes a statement to the effect that the project has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct ☐
3. I have made, and explained within this application, arrangements for any confidential material generated by the research to be stored securely within the University and, where appropriate, subsequently disposed of securely. ☐
4. I have made arrangements for expenses to be paid to participants in the research, if any, OR, if not, I have explained why not. ☐
5. EITHER
 - (a) The proposed research does not involve the taking of blood samples; ☐

OR
 - (b) For anyone whose proximity to the blood samples brings a risk of Hepatitis B, documentary evidence of immunity prior to the risk of exposure will be retained by the Head of School or authorized Head of Department. ☐

Signed:

..... Date.....
(Head of School or
authorised Head of Department)
6. EITHER
 - (a) The proposed research does not involve the storage of human tissue, as defined by the Human Tissue Act 2004; ☐

OR
 - (b) I have explained within the application how the requirements of the Human Tissue Act 2004 will be met. ☐

7. EITHER

- (a) The proposed research will not generate any information about the health of participants; ☐

OR

- (b) If the research could reveal adverse information regarding the health of participants, their consent to pass information on to their GP will be included in the consent form and in this circumstance I will inform the participant and their GP providing a copy of the relevant details to each and identifying by date of birth; ☐

OR

- (c) I have explained within the application why (b) above is not appropriate. ☐

8. EITHER

- (a) the proposed research does not involve children under the age of 5; ☐

OR

- (b) My Head of School (or authorised Head of Department) has given details of the proposed research to the University's insurance officer, and the research will not proceed until I have confirmation that insurance cover is in place. ☐

Signed:

..... Date.....
(Head of School or
authorised Head of Department)

This form and further relevant information (see Sections 5 (b)-(e) of the Notes for Guidance) should be returned to:

Dr Mike Proven
Coordinator for Quality Assurance in Research
Whiteknights House
Email: m.j.proven@reading.ac.uk

- both electronically and in hard copy

You will be notified of the Committee's decision as quickly as possible, and you should not proceed with the project until then.

Research Ethics Committee



Consent Form

1. I have read and had explained to me by
the accompanying Information Sheet relating to the project on:
.....
2. I have had explained to me the purposes of the project and what will be required of me, and any questions I have had have been answered to my satisfaction. I agree to the arrangements described in the Information Sheet in so far as they relate to my participation.
3. I understand that participation is entirely voluntary and that I have the right to withdraw from the project any time, and that this will be without detriment.
4. ***Researcher to delete (a) and (b) if GP will not be contacted, or (b) if no response from GP is required***
a) I authorise the Investigator to consult my General Practitioner.
b) I authorise my General Practitioner to disclose any information which may be relevant to my proposed participation in the project.
5. This project has been reviewed by the University Research Ethics Committee and has been given a favourable ethical opinion for conduct.
6. I have received a copy of this Consent Form and of the accompanying Information Sheet.

Name:

Date of birth:

Signed:

Date:

Research involving the taking of blood samples

Researchers should be aware of the provisions of the Human Tissue Act 2004, which regulates the consents required for the use or storage of "material which consists of, or includes, human cells", and requires that anyone storing such material for the purpose of research must have a licence from the Human Tissue Authority. The Department of Food and Nutritional Sciences has a licence for this purpose.

1. The Health and Safety Committee and the Research Ethics Committee have reviewed procedures relating to the taking of blood samples.
2. The arrangements which the two Committees have agreed are intended to safeguard the position of all those concerned without being unduly cumbersome in their operation.
3. Any person giving a blood sample, or a series of samples, is required to have signed the standard Consent Form (attached Annex D/1). The Consent Form should be retained by the Head of School but a copy should be made available to the person giving the sample if he or she so wishes.
4. The Consent Form includes a summary of the required procedures relating to the taking of blood samples. Heads of School are asked to ensure that these procedures are adhered to in their Schools. It has not been thought necessary to stipulate additional measures where it is the Head of School himself who is seeking the blood sample but Heads are reminded of the need for particular care in such cases.
5. Heads of School who wish non-medically qualified staff to be approved to take venous blood samples are advised to refer to the procedures in the Department of Food and Nutritional Sciences.
6. In all cases where blood samples are to be taken the Research Ethics Committee will require, as a condition of allowing the project to proceed, confirmation that for anyone whose proximity to the blood samples brings a risk of Hepatitis B, documentary evidence of protection prior to the risk of exposure will be retained by the Head of School (or authorised Head of Department)

The Taking of Blood Samples - Information Sheet and Consent Form

Information

1. Blood samples from staff or students must be taken only when the Head of School (or authorised Head of Department) has agreed that they are essential for teaching or research purposes. The Area Safety Officer must be informed and be satisfied that a suitable procedure for the safe handling, processing and storage of the samples is proposed. The Biological Safety Officer may be consulted for further information.
2. No individual, whether staff or student will be put under any pressure to agree to provide a blood sample. The Consent Form below must be signed by a provider of the sample(s) before the sample(s) is (are) taken. The provider may withdraw his/her willingness to provide a sample at any time.
3. The Head of School (or authorised Head of Department) and member of staff concerned are responsible for the safety of the procedure. Venous blood samples will be taken only by a) medically qualified staff, b) an approved member of staff following attendance and assessment on an accredited course or c) a member of staff who has been assessed by an approved trainer.

Consent Form

I have read the Information Sheet and been told the reasons why a blood sample is required. I consent to: **(delete 1 or 2)**

- (1) a single blood sample being taken
- (2) a series of blood samples being taken

Name Signature

Witnessed by:

Name Signature

Date

(This form is to be retained by the Head of School or authorised Head of Department.
A copy should be made available to the person providing the sample(s) if he or she wishes)

Guidelines to assist Heads of School (or authorised Heads of Departments) in defining research and therefore whether projects need to be referred to the University Research Ethics Committee

The purpose of this annexe is to help Schools decide if a project is research, which normally requires review by a School or University Research Ethics Committee (REC), or whether it is some other activity such as audit, or service evaluation. It draws on the National Research Ethics Service (NRES) Leaflet 'Defining Research' (December 2009)

The table below may help in differentiating the three categories

REQUIRES REC REVIEW	DOES NOT REQUIRE REC REVIEW	DOES NOT REQUIRE REC REVIEW
Research	Audit	Service Evaluation
Systematic investigation designed to attempt to generate knowledge. Includes studies that aim to produce hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best practice.	Designed and conducted solely to define or judge current practices.
Addresses clearly defined questions, aims and objectives. Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Measures against a pre-determined standard.	Measures without reference to a standard.
May involve the investigation of new theories / concepts and may involve carrying out experiments or less objective forms of measurement such as questionnaires, interviews, observation.	Involves only services / practices that are already firmly in use. Does not involve carrying out of experiments or the testing of new concepts / theories. Does not itself introduce any additional elements of choice.	Involves only services / practices that are already firmly in use. Does not involve carrying out of experiments or the testing of new concepts / theories. Does not itself introduce any additional elements of choice.
Usually involves collecting new data, although may include data already collected routinely.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
May involve allocating research participants to control / experimental groups. May involve randomisation	No allocation to control / experimental groups. No randomisation involved.	No allocation to control / experimental groups. No randomisation involved.

Key discriminants are:

- Intent

The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working. Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project.

- Treatment/service

Neither audit nor service evaluation uses an intervention without a firm basis of support in the clinical or health community.

- Allocation

Neither audit nor service evaluation allocate treatment or service by protocol. It is a joint decision by the clinician and patient.

- Randomisation

If randomisation is used, it is research.

Ethical Review

Projects which are considered to fall into the categories of (Clinical) Audit and Service Evaluation may be carried out by any staff or students, under suitable professional supervision and under an appropriate Code of Professional Conduct/Practice without reference to the Research Ethics Committee. However, the University's standard procedures and requirements with regard to consent and data protection should still be adhered to.

Projects which fall partly or wholly into the category of research must be referred to the School or University Research Ethics Committee as appropriate for review.

Annex F: University of Reading: Process of Ethical Review

