

**ETHICS GUIDELINES**

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 **Useful Links & Documents:**

 [Ethics Website](http://www.roehampton.ac.uk/Research/Ethics/)

 [Ethics Documentation Templates & Guidelines](http://www.roehampton.ac.uk/Research/Ethics/Ethics-Forms/)

 [Ethics Contacts](http://www.roehampton.ac.uk/Research/Ethics/Contact-Details/)

 [Link to University Policy Documents:](http://www.roehampton.ac.uk/Corporate-Information/Policies/)

 Lone Working Policy

 Safeguarding Children and Vulnerable Adults Policy

 Health & Safety Policy

 Data Protection Policy

 [Internal Guidance:](http://my.roehampton.ac.uk/information/researchoffice/Pages/EthicsFormsandGuidelines.aspx)

 Guidance Paper on the Disclosure of Illegal Activity

 Storage of Human Tissue

 Information on Human Tissue

ETHICS GUIDELINES

**1. TERMS OF REFERENCE**

1.1 Terms of Reference for the Ethics Committee

The role of the Ethics Committee is:

a) To consider on behalf of Senate and make recommendations on ethics policy of any of the following matters as they relate to activities undertaken under the University’s auspices by its students and staff, including associated research staff:

* any research projects using animals or human beings as participants;
* any teaching involving the use of animals or human beings or personal data relating to human beings;
* any form of clinical practice, treatment or counselling;
* sources and conditions of research funding; and
* any other activities using similar methods.

b) To consider and make recommendations on the policy regarding requests from researchers from outside the University seeking to use students and/ or staff as participants.

c) To establish and monitor Departmental procedures, including undertaking audits in order to ensure that staff and/ or students:

* are aware of the ethics issues involved in the work;
* observe the University's Ethics Guidelines.

d) To approve, or otherwise, applications for ethics approval for research, contract research and commercial development activities where existing policy is unclear in respect of the proposal being considered or where there is a particular risk to the University.

e) To put in place induction and training to introduce new members of the Ethics Committee to the business of ethics within the University, and to facilitate the continuing professional development of members of the Committees and academic staff.

f) To consider, and make recommendations to, the Library or to another appropriate authority in respect of requests relating to accessing and/ or using material which:

* might be considered offensive;
* might be considered to be in breach of the law.

g) To review, amend as appropriate and reissue from time to time the ‘Ethics Guidelines’.

h) To consider, report on and, as appropriate, make recommendations on such general or specific issues involving ethics considerations as arise within the Committee or are referred to it by Senate or by any other corporate body or individual members of staff or students of the University.

***Meeting Frequency***

Normally three meetings per year, with the option of further electronic meetings where appropriate.

***Servicing***

Ethics Committee will be serviced by the Research Office, Academic Enhancement Department.

***Composition***

* A chairperson drawn from senior academic staff within the University and selected by the VC\*
* A representative of Council\*
* An external lay member\*
* A student representative (not necessarily a research student)
* Deputy Provost (Graduate School)
* Director of Academic Enhancement Department
* Head of Health and Safety
* Legal Officer
* Four co-opted members with specific expertise as appropriate and necessary\*
* A representative from the Finance Department with knowledge of insurance matters, in attendance as required
* Secretary (nominated by the Research Office, Academic Enhancement Department

\* for a term of three years

Total membership: 13

**2 UNIVERSITY ETHICS PROCEDURE**

2.1 Ethics Requirements

In addition to the criteria outlined in terms of reference 1.1 any experiment or procedure which falls within one or more of the categories set out below must receive ethics approval:

a) procedures involving any risk to a participant's health (for example, intrusive physiological or psychological procedures);

b) topics, procedures and settings, the nature of which might be offensive, distressing or deeply personal for some members of the particular target group;

c) proposals which involve financial payments or payments in kind to participants (see section 3.4);

d) research or enterprise proposals to be carried out by persons unconnected with the University but wishing to use staff and/ or students of the University as participants under a formal arrangement;

e) any other proposal where the Head of Department considers that there are particular ethics issues making a decision difficult.

2.2 Assessment Process

All ethics documents are available to download from the ethics pages within the Research section of the University website

<http://www.roehampton.ac.uk/Research/Ethics/>

Staff and research student (PhD, MPhil, PsychD, EdD, MRes) ethics applications must follow the appropriate format and include the following\*:

*Ethics Application Form*

*Participant Consent Form* plus translations if required (using the suggested template)

*Ethics Risk Assessment Form*

*Ethics Overseas Background Information Form*

Any additional information

* for participants (e.g. questionnaires, debriefing form, correspondence)
* for other purposes(e.g. sample interview questions, advertisements)

*\* If a student or member of staff has transferred from another university or is conducting collaborative research with another external organisation(s), including the NHS, they may not need to complete these documents: please see the guidance at this end of this section.*

The ethics application should be sent by email to the Ethics Officer in the Research Office, Academic Enhancement Department, who will log the application, check the documents and upload them onto the Ethics Community on share point with a reference number for review by the Departmental Ethics Representative. Applications are not generally seen by the Ethics Committee (unless there is a specific reason for them to be referred) so are circulated to the Departmental Ethics Representatives as soon as possible after receipt. The aim is normally to turn applications around within four weeks. Applications should be submitted in good time to allow for the review process to be done, and an explanation should be provided if an application is submitted late. Retrospective applications may be considered but will also require the approval of the Ethics Committee Chair. The Departmental Ethics Representative should consider the application with reference to the University’s Ethics Guidelines and then complete the ethics approval form\* to:

1. approve the application
2. approve the application subject to conditions
3. ask the applicant to make substantial revisions and resubmit the application
4. refer the application to the Ethics Committee if there are particular reasons why the Department cannot reach a conclusion.

\* although some Departments prefer to ask applicants to address conditions beforehand so that a ‘clean’ approval form can be done.

The responsibility for consideration of ethics issues is devolved to the Department, and, as such, ethics applications are approved under the procedures of the University of Roehampton’s Ethics Committee. The Department must record the process by which ethics issues are considered on a case-by-case basis. The Head of Department (or their representative) should sign the ethics approval form, preferably with a scanned signature (a hard copy is not required), to confirm that the application has been assessed at Departmental level. This can also be done by proxy if the Head of Department is happy to do this. If the Head of Department has an interest in a project (e.g. as a co-investigator or Director of Studies) they can sign the ethics approval form but this will then need to be countersigned by the Ethics Committee Chair or Deputy (the Head of Department should not be the independent contact on consent forms in these circumstances).

The ethics approval form asks the Head of Department to confirm that the Department:

* approves the ethics application
* approves the participant consent form and any other information for participants
* confirms that an ethics risk assessment form (and an ethics overseas background information form if applicable) has been fully completed
* confirms that the project and the applicant has insurance cover
* confirms that appropriate facilities are available within the Department for the applicant to complete the project

Once the ethics application has been assessed by the Departmental Ethics Representative the signed ethics approval form should be sent electronically to the Ethics Officer, who will inform the applicant of the outcome via email.

If the applicant has been asked to respond to conditions, a deadline of two weeks will be requested for a response. Responses from the applicant to the conditions will be processed by the Ethics Officer. If the conditions require only simple changes to the documentation the Ethics Officer will confirm that these have been made. If the conditions require more significant changes then the Ethics Officer will ask the reviewer in the Department to confirm that the conditions have been met. Final email confirmation will then be sent to the applicant by the Ethics Officer, the date of which will be the date of final approval: this will confirm approval of the ethics application under the procedures of the University of Roehampton’s Ethics Committee. There is no time limit imposed for the duration of ethics approval for a project. However, we reserve the right to withdraw or change this at any point in the future.

2.3 Other Information

a) Ethics Information in a Thesis

On a standalone page or appendix the following phrase should be included in a thesis: “The research for this project was submitted for ethics consideration under the reference ……..in the Department of ... and was approved under the procedures of the University of Roehampton’s Ethics Committee on .....”

b) Ethics and RDB2

RDB2 and Ethics approval are separate, and ethics approval is not subject to RDB2 approval, although they should preferably be done in parallel. If changes to the project given in the RDB2 form have an impact on an ethics application, the Ethics Officer should be advised accordingly.

c) Bids

Although all ethics issues and risks should be addressed prior to submission of a bid, the review and approval of ethics applications is a separate process and researchers do not need to submit an ethics application or gain ethics approval for a project when applying for funding or before receiving confirmation that the application for funding has been successful (unless this is required by the funders). However, if tight deadlines are involved ethics applications should be submitted in good time, and the Ethics Officer should be advised of the timescales involved.

d) Minor Amendments

If a minor amendment to a previously approved project is required then the minor amendment form should be completed and sent to the Ethics Officer, along with any supporting documentation, for review by the Departmental Ethics Representative. If the amendment is considered to be more substantial then a new ethics application may be required.

e) Departmental Ethics Representatives

Only one Ethics Representative is required from each Department, to provide a central point of contact, but other staff (including PhD students) can be involved in the review process as the Department deems necessary, so long as discussions are confidential and conflicts of interest are declared. In Departments where there is no committee structure, if the Ethics Representative is unable to review an application they can request a suitably experienced colleague to do this in their place: they should ensure that the Head of Department approves the person selected and they should go through the review procedures with that person. Contact details for staff involved in the Ethics assessment process can be found on the Ethics website. Staff should not be involved in the review process for their own applications or if they have an interest in a project (e.g. as Director of Studies, Supervisor or co-investigator), although they will still act as the initial point of contact for the Ethics Officer. Outgoing Representatives should train incoming Representatives; the Chair and Ethics Officer will meet with new Representatives when they are appointed, and Representatives will also be assigned a mentor (a Representative from another Department) who will give feedback when reviewing their first application.

f) Ethics Committee

The Ethics Committee meets three times a year and is responsible for establishing and monitoring Departmental procedures, including undertaking audits in order to ensure that staff and/ or students are aware of the ethics issues involved in the work and that the University's Ethics Guidelines are observed. The Ethics Committee will also advise on problematic cases. If an application requires actual approval by the Ethics Committee (rather than being reviewed under its procedures) then this should be reviewed by the Department in the usual way but then forwarded via the Ethics Officer to the Ethics Committee Chair to confirm approval for the Ethics Committee by Chair’s Action. Five applications are selected at random, each one of which is from a different academic area, for audit at each Committee meeting. The Ethics Committee meeting minutes are circulated to the Departmental Ethics Representatives, with procedural changes highlighted for dissemination to their Departments via Departmental meetings.

g) Assessment Process for Students & Staff Transferring from another Institution

If a student or member of staff has already received ethics approval at their previous institution then they should send copies of their previous ethics application form, other documents and confirmation of ethics approval to the Ethics Officer. If the research will be published or conducted whilst at the University of Roehampton the Department will be asked to consider whether the approval documents from the previous university are sufficient. If the Department is satisfied with the ethics approval which has already been given they will inform the Ethics Officer who will record this centrally and advise the applicant. Applicants may be asked for additional information if the information provided is not considered to be sufficient. The contact details on consent forms should be amended to show the Roehampton details, and the University of Roehampton logo should be used on public-facing documentation where possible, provided that these documents have been approved through the above process. A student or member of staff will not normally be asked to complete the University of Roehampton ethics application form if they already have ethics approval from another university, unless the Department deems this to be necessary.

If a student or member of staff has not already received ethics approval for any part of their research at their previous institution they will need to follow the University’s standard ethics procedure as set out above.

h) Collaborative Research

If the University of Roehampton is the lead institution on a project, then an ethics application should be submitted following the University’s standard ethics procedure as set out above.

If a student or member of staff has received ethics approval at the host institution, or if Roehampton is not the lead University, then it is not usually necessary for a University of Roehampton ethics application form to be completed. A copy of the external ethics application form, other documents and confirmation of ethics approval should be sent to the Ethics Officer. The Department will be asked to consider whether the approval documents from the host institution are sufficient. If the Department is satisfied with the ethics approval which has been given they will inform the Ethics Officer who will record this centrally and advise the applicant. Applicants may be asked for additional information if the information provided is not considered to be sufficient – please see above.

If the University of Roehampton is the lead institution on a project and a second university is a partner, we generally ask for a copy of their ethics approval for our records. If a research project involves partners from other institutions (clubs/ agencies/ associations) and it is not appropriate or possible for them to be granted their own ethics approval, then they should be sent a copy of the ethics application form approved by us and should return a signed letter stating that 1) they have received this and read and understood the contents and 2) are happy to abide it and by the Ethics Guidelines as approved by the University of Roehampton.

The Ethics Committee Chair will be advised of any applications involving a collaborative organisation.

Please see 4.3 Ethics Approval from Collaborating Organisations for further information.

i)NHS Ethics Applications

All projects requiring NHS ethics approval are also subject to the full Roehampton ethics approval process. However, NHS application forms will be accepted in place of the standard University of Roehampton ethics application form. If a consent form is required an NHS template can be used as long as it includes the consent information as given on the Roehampton template, and all the contact information from our template is either added to the form or included in an information sheet; the Roehampton logo should appear at the top left of any forms. A Roehampton ethics risk assessment form is not required. The NHS application form and accompanying documents should be sent to the Ethics Officer and will be processed in the same way as a standard university ethics application. The NHS ethics application form itself will be signed off by the Ethics Committee Chair or Deputy Chair, and a sponsorship letter provided if required (this may not apply if the applicant’s employer (e.g. the NHS) is the sponsor rather than Roehampton. Applicants should not generally be ‘self-sponsored’). NHS ethics applications for undergraduate or postgraduate taught students (MA, MSc) should also be sent to the Ethics Officer, although the principal investigator will usually be the project Supervisor.

There may be occasions where a project involves the NHS but NHS approval is not required, for example if the study involves NHS staff and does not involve patient information. In such circumstances, it is the responsibility of the applicant to ascertain whether a project requires NHS ethics approval and, if not, to provide documentary evidence to support this as a condition of our approval. If no NHS application form is to be submitted, a Roehampton application form should be completed as usual.

Please see 4.3 Ethics Approval from Collaborating Organisationsfor further information.

2.4 Undergraduate/ Masters Research

Heads of Department must ensure that Programme Conveners of all programmes involving student research projects, where the credit attached to the project is less than 50% of the total credits required to obtain the award, (a) approve the topic and design of any project involving work of the kind specifically noted in these guidelines as requiring ethics approval and (b) ensure that an Undergraduate/ MA/ MSc ethics application form and consent form/ s are submitted and reviewed before the project begins and are included as part of the project when it is submitted for assessment. Where the credit attached to the project is 50% or more of the total credits required to obtain the award a separate Ethics Application must be approved through the process outlined in 2.2.

The form for undergraduate/ MA/ MSc research projects can be found on the Ethics website: this is a condensed version of the main ethics application form and also incorporates the consent form and debriefing form templates. Programmes may adapt these documents to suit their specific needs.

The review process for undergraduate, MA and MSc ethics applications should be overseen by the course Programme Convener. The decision as to who reviews these applications, and how, is a matter for each Programme. However, it is recommended that they be reviewed by two people, not just the Supervisor. An internal record of applications received and approved must be kept. **Please note that these applications and information should not be sent to the Ethics Officer**. If an application has more complex issues that might require further consideration, the Departmental Ethics Representative should be contacted to see if it should go via the central ethics process, or if specific issues need to be considered by the Ethics Committee (in which case the standard forms should be used). Please note that any projects that also require NHS ethics approval should go via the central ethics process.

Any projects involving the use and/ or storage of any human tissue, including blood sampling or the handling of blood and other body fluids, must be carried out in accordance with the University's policy\* on health and safety. Applicants should discuss their projects with the member of staff responsible for this (details can be obtained from the Ethics Officer) and include details in their ethics application. For more details please refer to the [Information on Human Tissues Documents.](http://my.roehampton.ac.uk/information/researchoffice/Pages/EthicsFormsandGuidelines.aspx)

Research projects for the University of Roehampton Certificate in Learning and Teaching in Higher Education are at MA level and should therefore be dealt with as above.

\* Including any Departmental arrangements, instructions or policies, the Joint Health and Safety Policy, the Lone Working Policy and the Under 18s Policy.

2.5 Responsibilities

Heads of Department are responsible for research, enterprise and teaching carried out within their Department and for those activities carried out under the supervision of their staff. It is the responsibility of Heads of Department to ensure that all staff are aware of the Ethics Guidelines and of the procedures for obtaining ethics approval.

In the case of students undertaking research, enterprise activities or conducting investigation, it is the responsibility of the Director of Studies, Programme Convenor or Module Convener to ensure that the students are aware of and observe the Ethics Guidelines, and any related Department protocols and procedures. Where the Ethics Guidelines refer to the need for action by the investigator, in the case of students it is the responsibility of the Director of Studies, Programme Convener or Module Convener to ensure that the action is undertaken.

2.6 Management of Risk

It is a University requirement that risk assessments should be conducted for all staff and student research or enterprise. Risk assessments should be completed for research or enterprise projects, both within and outside the University, beforework commences. The purpose of the risk assessment is to identify potential hazards, and hence control measures that might be needed. This is to help ensure the health, safety and welfare of the investigator and of any other person that might be affected by the work e.g. participants. Lone working should be taken into account: the link to the [Roehampton Lone Working Policy](http://www.roehampton.ac.uk/uploadedFiles/Pages_Assets/PDFs_and_Word_Docs/Policies/Lone-Working-Policy.pdf) is given here. Applicants should also identify and follow any health and safety procedures in the venues where the research is to be carried out.

An Ethics Risk Assessment Form should be completed by the investigator; for student work this should be in collaboration with the Supervisor. The Ethics Risk Assessment Form should be attached to the Ethics Application Form. For staff/ research student ethics applications this will then be reviewed by the Head of Health and Safety. Research students and staff working abroad for their research should also complete the Overseas Background Information Form (this includes researchers working in their country of residence if outside the UK).

It is the responsibility of the Head of Department to ensure that risk assessments are conducted for all research and enterprise projects being undertaken by their Department. Information on risk assessment is provided on the Ethics section of the website. Further advice can be obtained from the Head of Health and Safety.

2.7 Disclosure of Illegal Activity

There are some instances where there is a legal obligation to disclose information that may be obtained during research, such as terrorism or if a child is at risk. If a researcher thinks that this may be an issue they should discuss this with their Department and Departmental Ethics Representative in the first instance, then if necessary contact the University Legal Officer for advice. If required a phrase should be added to consent forms along the lines of “I understand that there may be some instances in which the investigator may be required to break confidentiality, such as if there are concerns about a serious harm to myself or others.”

For more information please see the [guidance paper](http://my.roehampton.ac.uk/information/researchoffice/Pages/EthicsFormsandGuidelines.aspx) on this subject.

2.8 Procedures for Appealing a Decision

If an applicant wishes to challenge a decision made by a Department in relation to an Ethics application then they should take this up with the Departmental Ethics Representative and Head of Department in the first instance. If the matter cannot be resolved this should be referred to the Ethics Committee for further consideration. The matter could then be considered at a special meeting of the Ethics Committee if required, with the attendance of other University Officers if necessary.

Any queries from participants or other parties regarding a research project should initially be referred to the Head of Department for further action as appropriate.

**3 THE GUIDELINES**

3.1 Ethics Documents of Professional and Other Bodies

The following acts, declarations and guidelines are concerned with research, enterprise and teaching involving human subjects. Further information regarding animal experimentation can be found under Section 4.8.

All teaching experiments, enterprise and research carried out in and by members of the University should conform with "The Universal Declaration of Human Rights and the Covenants on Human Rights" (UN General Assembly, December 1984) and with the University's Guidelines as set out below. Researchers should also consult the University of Roehampton Code of Good Research Practice.

Investigators are also required to observe the ethics guidelines advocated by their own appropriate Society or Professional Body.

* The Universal Declaration of Human Rights and the Covenants on Human Rights
* Declaration of Helsinki (updated 2013) – Ethics principles for medical research
* Singapore Statement on Research Integrity 2010
* The Concordat to Support Research Integrity 2012 – published by Universities UK
* The British Sociological Association - Statement of Ethics
* The Association of Social Anthropologists of the UK and the Commonwealth – Ethics Guidelines
* The British Psychological Society - Ethics Principles for Research with Human Subjects
* The Ergonomics Research Society - Ethics Standards for Research with Human Subjects
* The Medical Research Council - Responsibility in Investigations on Human Subjects
* The Social Research Association - Ethics Guidelines
* The Royal College of Physicians - Guidelines on the Practice of Ethics

 Committees in Medical Research Involving Human Subjects

* British Educational Research Association - Ethics Guidelines for Educational Research
* The Association for the Study of Animal Behaviour (ASAB)
* The Animals (Scientific Procedures) Act 1986

3.2 Teaching Experiments

The Ethics Committee considers that it is ethically acceptable to request an

undergraduate or postgraduate student to participate in physiological

experiments (e.g. using an exercise bicycle) or in experiments in the behavioural

sciences as a normal part of his/ her course, on the understanding that:

a) the supervisor ensures that all such studies conform with the Ethics

 Guidelines;

b) the student has the right to decline a particular procedure on any

 grounds, as participation is voluntary (a student can be required to

 engage in an activity if it is part of the course, but they do not have to

 consent to being a subject of research)

c) the student must be assured that, by declining to participate in a

 particular procedure, or by participating then subsequently withdrawing,

 his/ her course marks will NOT be adversely affected;

d) undue academic pressure or financial inducement should not be brought

 to bear on the student;

e) students may receive course credits for participation in staff and

 student research projects.

f) the policy and procedures outlined in section 3.8 must be observed

 when students are undertaking tests as a routine part of a programme of

 teaching or research from which unexpected results with possible health

 implications for the volunteers/ participants might arise;

g) the onus is on the members of staff in charge of the experiment to take

 reasonable steps to ascertain that the student is in good health and

 knows of no reason why s/ he should not participate.

3.3 Human Tissue

Research projects and teaching which involve the use and/ or storage of any human tissue, including taking blood and saliva samples and the handling of blood and other body fluids, must be carried out in accordance with the University's policy\* on health and safety. Generally samples (‘relevant materials’ as defined by the HTA, the Human Tissue Authority) may be stored and processed for up to a week without an HTA licence (the University does not hold a licence). Plasma and serum are not usually regarded as relevant materials under the act, but whole blood and saliva are. Although an HTA licence is not required for the storage of relevant materials if a project has approval from a recognised ethics committee (e.g. IRAS), a university ethics committee is not, for the purposes of the HTA, included as such. Applicants should discuss their projects with the member of staff responsible for this (details can be obtained from the Ethics Officer) and include these details in their ethics application. Participant consent forms should inform participants that the tissue they have donated will be destroyed after analysis or upon withdrawal from the project. For more details please refer to the [Information on Human Tissues Documents](http://my.roehampton.ac.uk/information/researchoffice/Pages/EthicsFormsandGuidelines.aspx), which include a list of relevant material under the HT Act.

\* Including any Departmental arrangements, instructions or policies, the Health and Safety Policy, the Lone Working Policy and the Under 18s Policy

3.4 Participants and Consent: the use of questionnaires, interviews and testing etc within and outside the University

NOTE: The words "questionnaire", “interview” and "testing" are used here on the assumption that they include any systematic technique for eliciting information by and/ or from any individual student, member of staff, other member of the University or member of the general public. Questionnaires should include the Roehampton logo at the top left of the page (if possible).

Consent

a) Consent to participate in a project should be obtained from all participants. This should be ‘informed’ consent so that the participants know what is involved and what they are agreeing to. The draft consent form template should be used but can be amended according to requirements: issues to consider include a brief outline of all parts of the project, information on how many people will be involved, where it will take place, how long participation will take and whether audio/ video recording/ photos will be used. The form should endeavour to be in the first person – i.e. addressed to the person who will be signing it.

b) It is recommended that the investigator supplies each participant with two copies of the consent form. One should be signed and returned to the investigator and the other should be retained by the participant for their information.

c) Deception: on occasions a researcher may not wish to divulge full details of the nature of participation as it may affect or bias the results by prior knowledge (although the full details will be given after the participation has taken place). Such deception is acceptable in principle, but any ethics application involving deception will require approval by the Ethics Committee or Ethics Committee Chair (although if the deception is essentially the same as previously approved studies this may not be required). In a research project with participants, if a participant is told there is ‘deception’ involved - e.g. they are told that there is going to be a control group, or that a placebo is going to be used for some participants, this is not considered to be deception as participants are informed: they know what is happening and consent to all scenarios involved.

d) The independent contact on consent forms should usually be the Head of Department (or the person who is signing the ethics approval form on their behalf). However, if the Head of Department has an interest in a project, then an alternative may be used, such as a stand in for Head of Department, the Departmental Ethics Representative or the Ethics Committee Chair/ Deputy if they are countersigning the approval form.

e) Verbal Consent: there may be occasions where a signed consent form cannot be obtained. Although consent forms should be used if possible, verbal consent is acceptable in principle in particular cases, as long as details of the process are recorded.

f) Withdrawal: the University takes the position that participant withdrawal from a project can be at any time, although a statement should be added to the consent form such as “please note, however, that data may still be used in a collated form” to acknowledge that it would not be possible to remove data from a written-up report etc. Otherwise consent forms should specify a final date for participant withdrawal.

g) Anonymity for participants is usually the default position. If names of participants are required, researchers should confirm with participants that they agree for their names to be used.

h) There may be occasions when a researcher is required to break confidentiality, such as if there are concerns about a serious harm to a participant or others. If this is the case, a sentence regarding this should be added to the consent form.

i) Consent should normally be obtained through the use of the University’s participant consent form. ‘Opt in’ consent is the standard procedure where all participants are required to complete a consent form. If the investigator wishes to use ‘opt out’ consent then the reasons for this must be made clear in the ethics application and it will the responsibility of the Department to determine whether this is appropriate. Any request for ‘opt out’ consent in schools will be considered on a case by case basis.

j) Working with Participants under the age of 18: all applications for projects involving participants who are under 18 must address the particular issues raised. Particular concerns when working with participants who are under 18 may include obtaining parental consent, child protection issues, use of images etc. In the ethics application the investigator must explain how these concerns will be addressed in accordance with the Safeguarding Children and Vulnerable Adults Policy. If the project involves working with 16-17 year olds consent is required from both the parent and the young person. The investigator should also clarify that any legal requirements have been met, e.g. DBS clearance.

k) Consent in Schools: if a teacher is the focus of the research then there is no need to obtain consent from parents of children in the class unless the school stipulates otherwise. However, should the children become the focus of the observation then this would require written consent from all parties (teacher, head teacher, parents and (possibly) children) because their data will be used. If children are receiving content, activity or experience as specified for the benefit of the researcher (not part of their normal curriculum), then further consent would be required.

l) Written permission to recruit or carry out research should be obtained as necessary from all organisations involved (email confirmation of this is acceptable). If an organisation is actually taking part in a project then a consent form will be required for that organisation. Permission should also have been obtained as appropriate to display recruitment material.

DBS (Disclosure & Barring Service)

 DBS: a Disclosure Statement may be required for research involving sole access to activities with either children (under 18) or vulnerable adults. This is an official document issued by the Disclosure & Barring Service (DBS), formally the Criminal Records Bureau (CRB), providing details of a person’s conviction record, including cautions, reprimands and warnings held on the Police National Computer. This is usually only required if the work/ research involves ‘regulated’ activity with either children or adults, for example:

Children

* Sole access to unsupervised activities on a frequent basis, teaching, training or instruction, care of supervision, advice or guidance on wellbeing, or driving a vehicle for children
* Work in a specified place on a frequent basis with opportunity for contact, including schools and children’s homes.

Adults

The definition focuses on the nature of activities which, if required by an adult, will define them to be vulnerable. So for example:

* Health care
* Personal care

 A definition of vulnerable is difficult to establish, but the main areas of concern are the ability to give informed consent and coercion.

The application process for DBS clearance is online. To arrange this staff and research students (PhD, MPhil, PsychD, EdD, MRes) should contact Human Resources (undergraduate, MA and MSc students should contact Student Admissions) and they will initiate the process. A DBS check is only valid on the day that it is done, and the older the check, the less comprehensive it may be. It is suggested that if required a check should be done every 3 years. We do not generally accept DBS checks from another institution.

 If a DBS check would be required for research to be undertaken in this country, then we also require this for researching overseas. Although a researcher living abroad and conducting research there could not request a UK DBS check as they would not have a UK address, they should check with Human Resources in the same way as if researching in the UK. Applicants should also confirm that they will abide by the local requirements of the country concerned in relation to obtaining the equivalent of a UK DBS check, as well as requirements relevant to the UK in this regard.

**If in doubt whether a DBS check is required, applicants should contact Human Resources**.

<https://www.gov.uk/disclosure-barring-service-check/overview>

General Information

a) When the questionnaire or content of the interview is of a potentially offensive, distressing or of a deeply personal nature, or when there are special reasons why any of the guidelines below are not observed, this should be explained in the ethics application. Applicants are asked to include copies of questionnaires/ interview protocol/ sample interview questions with the ethics application for consideration by the Departmental Ethics Representative. However unless there are particular circumstances as detailed in the ethics application, the following guidelines should be observed.

b) The purpose of the questionnaire, interview or test should be clearly defined by the investigator who has a responsibility to explain as fully as possible (i.e. without prejudicing the objectives of the study) what the project is about, who is undertaking and financing it, and why it is being undertaken. Where the full nature of the study cannot be revealed without prejudicing the objectives, the purpose of the questionnaire, interview or test, and the reason why it could not be fully revealed from the start, should be explained after the event (see section on deception above).

c) When the subject is a student, the investigator or tester should inform the student if completion of a questionnaire or interview or attendance at a test is an obligatory part of the student's coursework, or will in any way contribute to the student's final assessment.

d) Applicants should confirm that there is no compulsion or academic pressure to take part in the project, and that should a student decline to participate or subsequently withdraw, their course marks will not be adversely affected.

e) Whenever reasonably practicable signed consent or equivalent of the recipient of a questionnaire should be sought before its issue. A signed consent form may not be required for completion of questionnaires by the public (as completion and returning of the questionnaire itself is taken as indicating consent). The questionnaire should include a section stating that the completion and handing in of the questionnaire is taken to mean that consent has been given. An information sheet bearing the Roehampton logo is required for participants to keep, and this should advise that withdrawal is not possible as completion is anonymous.

f) The manner in which the questionnaire is presented should give the recipient the right not to participate.

g) Online Questionnaires: if an online questionnaire is to be used, the applicant should take the following into account: confidentiality and security of the software site used; age (confirmation is required that participants are 18 or over); there should be a consent page comparable to the standard consent form template, including contact details; participants should be able to print the consent form and final/ debriefing page; information about how withdrawal is to be handled is required.

h) Notwithstanding the agreement of a subject to participate in any questionnaire survey, interview or testing covered by the guidelines above, he or she may at any stage withdraw that agreement.

i) The information from any individual questionnaire or interview should remain confidential, and the anonymity of the respondents should be preserved. Participants’ scores are not generally divulged to them.

j) Publishing or divulging to another person, Department or investigator information from which individual identity may be deduced, may be done only with the written consent of the individuals concerned immediately prior to publication.

k) In any case where there occurs either a deliberate or accidental breach of confidentiality, the individual conducting the survey or testing will be held responsible.

l) Any investigator processing personal data by electronic means should be aware of and comply with the provisions of the Data Protection Act, 1998 (see Section 4.10).

m) It is permissible for a research worker, member of staff or any other member of the University to display notices calling for volunteers to answer questionnaires or participate in any form of research, or service testing, subject to the normal courtesies and rules governing the use of notice boards, pigeon holes and circulation systems. These notices should aim to give sufficient details about the commitment involved. They should show the Roehampton logo at the top left.

n) A student, employee or other member of the University is free to participate as a volunteer in any form of questionnaire, survey, research or service testing, except during hours specifically timetabled for academic purposes (or other normal working hours) when the consent of the appropriate Head of Department should be sought by the person conducting the enquiry.

o) As a matter of courtesy, any undertaking given to participants by the investigator must be honoured, even if the information gathered is not to be used subsequently. For example, if householders are told that questionnaires will be collected then arrangements should be made to do this.

p) Where staff and/ or students of the University are included among the subjects of the study, particular care must be taken to preserve their anonymity.

q) Selection of participants based on status (including majority status) is acceptable with appropriate context (e.g. on recruitment posters).

r) Social media and the internet: applicants intending to use social media and the internet in their research should consider such things as whether and to what extent information from these sites is in the public domain, whether their research is within the terms of reference and conditions for the site used, anonymity and confidentiality, the issue of deception where websites are created as part of research, and reputational risk for the University. This information may need to be reflected in the consent form. The [BPS Ethics Guidelines on Internet-mediated Research](http://www.bps.org.uk/) can be consulted for further information. Other useful information can be found at the [Association of Internet Researchers](http://aoir.org/ethics/).

s) Debriefing: a debriefing form may be used if required. This should include contact details for the researcher, Director of Studies if applicable and Head of Department as on the consent form. It should also include details of support services such as the Student Welfare Officers and Student Medical Centre (if participants are Roehampton students), and may advise participants to contact their GP (or perhaps other organisations) if they have any concerns.

t) If a transcription service is used, then a confidentiality agreement should be obtained and included in the ethics documentation.

Reimbursement of Participants

a) HM Revenues and Customs view is that reimbursement to cover expenses and some compensation for time is reasonable. What is deemed to be a reasonable amount may differ with different projects, but under £ 50 might be considered to be appropriate. The sums given should be for any inconvenience involved in participation. Staff can also participate provided that the activity is not linked to their day to day work and that it does not take place within their normal working hours. However if the sums paid are to go beyond “reasonable” then they may be liable to tax and NI.

b) If a higher payment is required this should be agreed with the Finance Office via the Department.

c) Reimbursement should be made by vouchers where possible.

d)Payment can be linked to performance but this must be clearly stated on consent forms, and all participants must be paid.

e) Payment to participants who are working on a contract with the University is permitted provided that the right to withdraw is maintained and that payments cease at the point of withdrawal.

f)Prize draws: the use of prize draws is acceptable in principle, provided that the maximum prize is £ 50 and gift vouchers are ideally used although cash can be used instead.

3.5 Obtaining consent from participants who may be involved in research indirectly

a) Investigators need to be aware that there may be occasions where a volunteer participant in a research project provides data which includes references to a third party such that, although the identity of the volunteer is safeguarded, there is a possibility that the third party might be identified. In such a situation the investigator needs to assess the risk of such identification happening, the likely implications of identification and the feasibility of securing the informed consent of the third party to the use of the data.

b) If the risk is thought to be significant, and securing consent is feasible, the investigator should seek consent before publication. If the risk is thought to be significant and securing consent is not feasible, the investigator must consider carefully whether the nature of the material is such that it ought to be excluded completely from any published report. In some cases, the report, or some sections of the report, should be categorised as ‘restricted access’ and anyone seeking access should be asked to sign a statement guaranteeing that the material will not be made public in ways which will reveal the identity of the third party.

c) If the investigator concludes that the unrestricted publication of the material is essential to the full and proper reporting of the research outcomes, s/ he must take all possible steps to protect the identity of the third party.

3.6 Access to records of students' work

a) The Ethics Committee may request the Academic Registrar, University Secretariat to consider which students' marks might suitably be made available and in what form for bona fide research purposes.

b) Confidentiality of individual students' marks should be maintained at all stages and full anonymity preserved in any research or other reports which might arise.

3.7 Hazards to health which might be occasioned by medical/ clinical trials (e.g. all drug trials and the administration of drugs and other substances in pharmacological doses for research purposes)

Studies involving blood sampling or the handling of blood and other body fluids must be carried out in accordance with the University's policy on health and safety (see also section 3.3 above) and be the subject of a risk assessment.

Any ethics applications involving medical/ clinical trials will also be referred to Finance to confirm that insurance cover is in place.

a) Approval for the use of an untried drug produced by a commercial company should be referred in the first instance to the Commission on Human Medicines: The Medicines and Healthcare Products Regulatory Agency (MHRA) (‘the MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe’) and written evidence of approval must be obtained and submitted to the Ethics Committee.

b) In every case a letter should be obtained from any drug company concerned, giving complete and accurate information concerning the trial, and confirming that company's acceptance of full legal liability for any malconsequences. (See also the note on Insurance, Section 4.2.)

c) The administration of drugs should be carried out under the supervision of a registered medical practitioner.

d) Every instance of a proposal involving the administration of drugs to participants should be presented to the Ethics Committee notwithstanding the fact that it might appear to comply with these Guidelines.

e) In cases where a proposal necessitating the administration or trials of drugs to or on participants involves financial inducements to the subjects, details relating to the amount of financial inducement and the nature of the drug should be notified to the Ethics Committee at the time of submission.

f) Participants in drug trials/ bioavailability testing should not normally be undergraduate students.

g) It is permissible for a research worker, member of staff or any other member of the University to display notices calling for volunteers to answer questionnaires or participate in any form of research or service testing, subject to the normal courtesies and rules governing the use of notice boards, pigeon holes and circulation systems. These notices should aim to give sufficient details about the commitment involved. They should show the Roehampton logo at the top left. Permission should also have been obtained as appropriate to display recruitment material.

h) Full information on official headed paper should be made available to prospective participants soon after the initial call for volunteers to a particular study.

i) If there are any doubts whether the experimentation involves risks of an abnormal nature (i.e. abnormal in relation to the usual run of experiments in the University) confirmation of insurance cover is required (see also Section 4.2 on insurance).

j) In the case of undergraduate or other participants, nobody under the age of 18 should be allowed to participate without written parental consent.

k) The supervisor should require from each participant a signed statement certifying his/ her informed consent to the experimentation.

l) The participant has the right to withdraw from the experimentation at any stage, and it is the responsibility of the investigator to make this understood in advance.

m) For any participant in a drug trial, it is the responsibility of the supervisor to notify the participant's General Medical Practitioner prior to the commencement of the trial. This must be confirmed in the consent form.

n) The investigator should notify the appropriate Head of Department of the identity of each participant who is a student or member of staff.

o) Where there is substantial interference with the work of the Department, caused either directly or indirectly through loss of time and/ or efficiency of the participant, the relevant Head of Department should have the right to withdraw that student or member of staff from the medical/ clinical trials.

p) Arrangements should be made by the supervisor for all participants engaging in medical/ clinical trials to be medically screened before the trials begin, and copies of medical reports should be retained by the supervisor until six months after the end of the trials, when the records must be destroyed.

q) The Department must be informed and consulted if any significant material change is made to a protocol that has already been approved.

r) Any significant untoward event occurring during or as a result of a study affecting a participant should be communicated promptly to the participant's General Practitioner, and be drawn to the attention of the Department/ Committee.

3.8 Hazards to health which might be occasioned by physiological experiments and measurements involving the inducement of more than minimal stress by, for example, isolation, fasting, sleep deprivation, noise, exercise, exposure, submersion and electronic means

In most cases the Guidelines for drugs trials (section 3.7) should also be used to cover hazards to health occasioned by physiological experiments and measurements, except that additionally:

a) Every instance of a proposal involving physiological experiments and measurements of the type exemplified above should be presented to the Ethics Committee notwithstanding the fact that it might appear to comply with these Guidelines.

b) The Department/ Ethics Committee may require that such experimentation should be carried out under the supervision of a registered medical practitioner.

c) In cases where a proposal involves financial inducements to the subjects, details relating to the amount of financial inducement should be notified to the Department/ Ethics Committee in the ethics application.

3.9 Policy and procedures relating to students undertaking tests as a routine part of a programme of teaching or research arising from which unexpected results with possible health implications might occur

In these circumstances a risk assessment should have been carried out by the academic supervisor before the project/ class/ experiment takes place. At the outset of appropriate projects/ classes/ experiments it is the duty of the academic supervisor to indicate to those concerned (participants/ investigators) that some apparently untoward results may be obtained, and to draw the students' attention to the notes on the schedule referring to participation.

i) In any practical teaching or research schedule in which ill-health in a subject may be discovered incidentally, the following information should be included in writing or displayed.

 Participants will be asked to participate on the understanding that:

 a) the procedure is explained and understood to be entirely voluntary;

 b) the participant has a right to decline to participate or, having accepted, to withdraw at any time;

1. neither declining nor accepting to participate will affect the assessment of coursework in any way;
2. the student is in good health and know of no reason why s/he should not participate.

ii) In the event of untoward results being obtained, the following procedure should be adopted by the supervisor where s/he alone is the investigator.

 a) Advise the participant that there are wide variations between individuals.

 b) Avoid the concept of "normal/ abnormal" but employ rather the concept of "a range of reference values".

 c) Reassure the participant that untoward results in research are not uncommon and do not necessarily have implications for health.

 d) Resist any attempt to interpret the results in the Department - particularly in terms of medical significance or diagnosis.

 e) Advise the participant (if s/ he is still anxious) to consult a medical practitioner in the first instance. The onus will be on the subject to take or disregard the advice.

iii) Where the student is acting as investigator:

 a) the procedures in sections (i) and (ii) above should be explained to the student by the supervisor, including the requirement of any investigator to treat any results with the strictest confidence;

* + 1. where any untoward result is obtained, the investigator should

 report the matter as soon as possible to his/ her supervisor, who

 will then take appropriate action.

**4 GENERAL CONSIDERATIONS**

4.1 Guidelines for external involvement in the funding of research, enterprise or other projects

For the purposes of these guidelines 'external involvement' is defined as any involvement with a body, external to the University, that generates income to fund a research or other project.

External involvement in the funding of research or other projects is welcome by the University but at the same time the University must maintain its integrity and uphold its values as outlined in its [Mission Statement](http://www.roehampton.ac.uk/About-us/). These guidelines are designed not to be prescriptive but to help members of staff and research students of the University to ensure that any external involvement in the funding of a research or other project does not undermine either the integrity of the University or its values.

It is important that funding should not be sought or accepted from any source to undertake a research or other project, the aims and objectives of which would conflict with the University's Mission Statement or undermine the integrity of the University.

The provider of funding for a research or other project:

* should not prejudice the outcome of the project or curtail publication of the results;
* should be asked, where appropriate, to declare any interests that might conflict with the University's Mission Statement or might be prejudicial to the outcome of a project or might undermine the integrity of the University;
* should not have a mission or aims that conflict with the University's Mission Statement or would undermine the integrity of the University;
* should not impose any terms or conditions to the funding that are inconsistent with University policy, the University's financial regulations, or conflict with the University's Mission Statement.

Some examples of providers of funding that might raise ethics issues that

would need careful consideration before the University accepted the funding

are:

* those whose main business is armaments
* those whose main business is gambling
* those whose main business is tobacco
* those who have a record of abuse of human or animal rights or the environment as legally defined
* those who do not support the values outlined in the University's Mission Statement
* those whose reputation is such that it would bring the University's name into disrepute through being associated with them.

This list is by no means a definitive list, nor is it meant to be, and in cases of doubt advice should be sought (see below).

Some examples of providers of funding that the University would encourage are:

* those who provide goods or services of value to the community
* those whose practice encourages fair trade
* those who show respect for human and animal rights or the environment
* those who promote or contribute to the promotion of the values outlined in the University's Mission Statement.

As a rule funding from the UK research funding councils and government bodies/ departments (AHRC, BBSRC, British Council, CCETSW, ESRC, EPSRC, MRC, Ministry of Agriculture, Fisheries and Food, NERC, PPARC, LEAs, local government offices, local councils, TECs) would be deemed an appropriate source of funding.

Similarly, funding from EU bodies/ research funding schemes (for example, Framework Programmes) would be deemed an appropriate source of funding.

If in doubt about the appropriateness of the source of funding for a research project, clarification should be sought from the Head of Department, the Departmental Research Facilitator or the Academic Enhancement Office. If in doubt about the appropriateness of the source of funding for a non-research project, clarification should be sought from the Departmental Research Facilitator or the Academic Enhancement Office.

4.2 Insurance

The University's Insurers are satisfied that the risks envisaged in the Guidelines in Section 3 are covered by the University's Third Party and Officials' Indemnity policies with the exception of externally funded clinical trials. Investigators who fail to follow the Guidelines are warned that they risk not being covered by the University's insurance.

a) Projects involving abnormal risk (including clinical trials)

#### The current Public Liability insurance cover through Zurich UK only covers the University for internally funded clinical trials (excluding USA and Canada). Internal clinical trials conducted by students are also covered provided that they are carrying out their work under supervision and there is written evidence to support that this supervision is taking place such as a laboratory log book. The University does not currently have insurance cover for externally funded clinical trials. It is necessary for investigators to advise the Head of Finance, who should in turn inform the insurers, of any experiment which is a clinical trial or might involve abnormal risk. The University also needs to inform the insurers where the trial is conducted outside the UK.

b) Projects involving administering a substance

Insurance cover should be confirmed for projects involving any substance is being given to a participant (even if it is just a drink or food commercially available). This is required as we are administering it/ organising it as part of the project, even though the participants may be taking it in their own home, and even if it is commercially available.

c) Staff and students working abroad

Students and staff working abroad for their research should have completed the overseas background Information form for their ethics application (this includes researchers working in their country of residence if outside the UK). Staff and students working abroad should check the Foreign and Commonwealth Office website for current travel advice regarding the country in question, <https://www.gov.uk/foreign-travel-advice> and should refer to [www.nathnac.org](http://www.nathnac.org) in respect of disease risks to travellers. Applicants should adhere to the [University guidelines on foreign travel (Business Travel Cover)](http://my.roehampton.ac.uk/information/researchoffice/Pages/EthicsFormsandGuidelines.aspx). A level of insurance cover is in place for students working abroad in all countries provided there is evidence of appropriate supervision. However, please note that exclusions may apply depending on the country visited and applicants are advised to check insurance cover with the Finance Office. The Ethics Officer will confirm that insurance cover is in place for both the project and the individual via Finance Department as part of the ethics application process.

At least one month before the intended travel date an ethics risk assessment form and overseas background information form should have been completed (see the template on the Ethics web pages). Advice can be obtained from the Head of Health and Safety.

Students and supervisors should:

* Keep detailed documentation of all conversations/ email contact during the overseas fieldwork;
* Agree the milestones and reports to be provided at each milestone;
* Have contingency plans to resolve any problems/ issues that may arise during the overseas fieldwork;
* If possible, arrange a local supervisor to provide support during the overseas fieldwork.

4.3 Ethics approval from collaborating organisations

Research protocols which involve access to subjects under the day-to-day care of another institution (for example, a hospital, clinic, University or school) will need to produce evidence that the investigator has the agreement of the appropriate authority at the institution concerned. In the case of a hospital or clinic the appropriate authority is the Ethics Committee of that institution.

Proposals which involve the use of facilities or access to participants on premises outside the University must also secure ethics clearance from the collaborating organisation. For example, for research which uses hospital, clinical or other premises not available to the University, investigators will need to produce evidence that they have the agreement of the Ethics Committee of the hospital, clinic or other organisation concerned.

Please note that for collaborative research it may not be necessary to complete the University of Roehampton ethics application form. Please see Section 2.2 Assessment Process for further details.

4.4 Proposals for ethics approval from Associated Institutions

The Ethics Committee will allow Departments to consider and approve proposals from those of the University’s Associated Institutions that do not have Ethics Committees of their own, provided that the proposals arise directly or indirectly from courses which are validated by the University of Roehampton.

Unless a Roehampton collaborative provision partner has an established ethics process which is approved by Roehampton, they should adopt the Roehampton Ethics Guidelines and documentation templates for implementation locally. The Memoranda of Understanding and/ or contracts between these organisations and ourselves should include wording to this effect.

Under these circumstances the Committee (or representatives thereof) would reserve the right to inspect the appropriate premises and facilities within the Associated Institution.

4.5 Investigators from outside the University seeking to use students and/ or staff of the University as participants

a) An investigator from another organisation who wishes to use University of Roehampton staff and/ or students as participants is only required to submit an ethics application through the University processes if the project involves a formal arrangement with the University (e.g. the investigator wishes to use students on a particular course as participants or will be using university facilities). If participants are being informally invited to participant in research (e.g. an online survey or posters) then a university ethics application is not required. However we would usually expect the investigator to have been granted ethics approval by their own organisation. Permission should also have been obtained as appropriate to display recruitment material.

b) Investigators from outside the University wishing to use University students and/ or staff as participants in a formal arrangement must first seek an academic ’assessor’ from within the University, who is independent of the investigators. The assessor will be responsible for assessing that the proposal is reasonable and falls within the provisions of the Guidelines.

c) The ethics application should be submitted to the Ethics Officer and be processed through the standard assessment procedure.

d) All proposals by an external sponsor or sponsors wishing to use students and/ or staff as participants through a formal arrangement with the university must be submitted to the Ethics Officer and be processed through the standard assessment procedure. All such proposals must be accompanied by a statement by the sponsor(s) accepting full responsibility for any malconsequences.

e) In the interest of the students concerned, the names of any students taking part as participants in projects involving medical or psychological experimentation (see also sections 3.7 and 3.8 above) undertaken by investigators from outside the University, whether these projects are externally or University based, should be submitted to the Ethics Committee. This information will be subject to the usual rules for the maintenance of medical confidentiality.

4.6 Contract work involving the evaluation of intended proprietary medicines or medical appliances, using students or others, and involving financial inducements, particularly where the objectives are mainly commercial and/ or where the work undertaken does not constitute scientific research

In every instance of a contract/ project involving the evaluation of intended proprietary medicines or medical appliances, using students, members of staff or others, and involving financial inducements to the participants, the details of that contract/ project should be included with the ethics application and should include details of the amount of financial inducement involved, the nature of the contract and the medicine or appliance to be evaluated.

4.7 Personal payments to investigators or Departments

Personal payments received by investigators, and their pecuniary relationship with any sponsoring company, have ethics implications. Details of specific payments to investigators or Departments should be included in the ethics application form. This information will be kept in confidence.

Investigators who receive payment as part of an annual consultancy fee should advise the Committee of this situation, but details of such payments would not normally be declared.

4.8 Experimentation on Animals

The University recognises that sometimes animal experimentation is necessary in order to further scientific knowledge and understanding. Animal experimentation encompasses all research, teaching or consultancy work using animals, including that using cells and tissue. We also include research involving animal observation. All ethics applications involving animals that incorporate new and unusual procedures that have not previously been approved will be referred to the Ethics Committee Chair to approve in principle (the application will still need to go to the Department for review in the usual way). Ethics approval is not normally required for projects involving invertebrates (the only exception being *Octopus vulgaris*.

When considering proposals for such work, Departments and the University Ethics Committee will use the following policy statements in deciding whether to approve or reject such applications:

a) The sources of any external funding to support animal experimentation should be considered in the light of the current Ethics Guidelines.

b) Some of this work might involve the need for Home Office approval depending on the nature of the proposed study and the animal species involved. Any proposal which a Department has approved but which is subject to the granting of a project license, a personal license or a Certificate of designation from the Home Office, must also be considered in detail by the University Ethics Committee to ensure that the procedures will be conducted according to Home Office guidelines and the University’s ethics policy.

c) It is recognised that most proposals will not require that the University need apply for licensing. However, the Department and the University Ethics Committee will need to be satisfied that the general principals relating to animal welfare required under the Animals (Scientific Procedures) Act 1986 will also be applied to such unlicensed work. This includes determining that there are no scientifically suitable alternatives that **Replace** animal use, **Reduce** the number of animals needed or **Refine** the procedures used to cause less suffering (known as the 3Rs).

d) Proposals need to demonstrate that the work envisaged will not have an adverse effect on species or habitats that are considered endangered.

e) Where proposals are received for work overseas, whether undertaken collaboratively or not, it should be demonstrated in the application that the work is not being carried out in this way so as to deliberately circumvent the provisions of the Animals (Scientific Procedures) Act 1986 or any other relevant Acts of Parliament.

f) All work involving animal experimentation carried out by students or staff of the University outside the United Kingdom must conform to the provisions of the Animals (Scientific Procedures) Act 1986. Any such application should also demonstrate the proposed work is in accordance with the relevant local legislation and that the ethics guidelines of any partner institution involved in the work are consistent with those of Roehampton.

g) All applicants for work involving animal experimentation carried out by the University’s students or staff in collaboration with any other institution(s) in the United Kingdom should also demonstrate that the proposal has the approval of the ethics committee(s) of the partner institution(s).

h) For projects involving animal observation applicants should address potential risks in their ethics applications, such as the possibility of attack (bites/ scratches) from animals being observed, and the handling of samples.

Selected Extracts from the Guidance on the operation of the Animals (Scientific Procedures) Act 1986 to assist Departments and the University Ethics Committee (entitled [Ethical Issues relating to Animal Experimentation](http://www.roehampton.ac.uk/Research/Ethics/Ethics-Forms/)) are available as a separate document.

4.9 Morbid anatomy

Experimentation in morbid anatomy is strictly controlled by licence from the Secretary of State for Health and falls outside the scope of these guidelines.

4.10 Data Collection and Retention

Research data should be stored for at least 10 years. Ethics applications are also stored for 10 years from the date of approval. It is permissible for hard copies of documents to be scanned and stored digitally. Paper versions can then be securely destroyed. Digitised files should be labelled, organised and backed-up appropriately

Investigators must adhere to the University’s *Code of Good Research Practice* and *Data Protection Policy*. The following are extracts and the full policy documents can be found on the University website.

4.10.1 *Section 2.7 of the Code of Good Research Practice*

a) Research data must be recordedaccurately (where appropriate,

signed and dated by the investigator) andin a durable and auditable form, with appropriate references so that it can be readily recovered.

b) Research data must normallybe retained intact for a period of at least

ten years from the date of any publication on which it is based. Investigators should be aware that specific professional bodies and research councils may require a longer period of data retention.

c) It is the duty of the principal investigator in any research project to comply with the regulations of the current Data Protection Act in force from time to time and to ensure that copyright, a third party’s intellectual property rights and confidentiality are not breached.

d) Specific arrangements should be made to protect the security of

research data where there is a contractual or ethics requirement to do so.

e) In general, academic enquiry and debate require openness but

confidentiality provisions relating to publication may apply in circumstances where the University or the investigator has made or given confidentiality undertakings to third parties or confidentiality is required to protect intellectual property rights. It is the obligation of the investigator to ascertain whether confidentiality provisions apply and of the Head of Department to inform investigators of their obligations with respect to these provisions.

4.10.2 *Sections 3 and 4 of the Data Protection Policy*

Section 3 - The Data Protection Act 1998

The Data Protection Act 1998 amplifies the provisions of the Data Protection Act 1984, redefining some of its terms and extending its scope. The area of data protection in the UK is controlled by the Information Commissioner, with whom the University is registered.

The main aims of the Act are, firstly, to require data users to be open about the collection and disclosure of personal data and to ensure adherence to a series of principles that are designed to prevent the misuse of data. Secondly, the Act attempts to guard everybody from any harm or distress which could be caused by information getting into the wrong hands. Thirdly, the Act accords to individuals a number of rights in respect of access to, information about and prohibition in the processing of data.

There are requirements for notification, previously called ‘registration’, of the processing of data to the Office of the Information Commissioner. This process involves the completion of a detailed form for each use of data, for example personnel/employee administration, research and strategic analysis and education and training administration.

The University’s entry on the register of the Information Commissioner is a substantial document: the Notification can be viewed at <http://ico.org.uk/ESDWebPages/DoSearch> Registration reference: Z8395749.

* 1. The Act outlines eight Data Protection Principles:
		1. *Personal data shall be processed fairly and lawfully*

*In practice what this means for the processing of information is that the University can, subject to certain limitations, process personal information in the normal course of administration. Examples of typical uses of information are:*

* *Recruitment*
* *Administration and payment of wages, salaries, pensions and other benefits*
* *Negotiation or communication with employees*
* *Employee assessment and training, manpower and career planning*
* *Compliance with policy and/or legislation with regard to health, safety or other employment matters*
* *Job or task scheduling or roster administration*
* *Identification of resources*
* *Monitoring the use of equipment, vehicles or services*
* *Analysis for management purposes and statutory returns*
* *Provision of references*
* *Student admission and registration*
* *Academic progress of students.*

*Sensitive data will only be held and processed in one of the following circumstances:*

* *If the data subject has given his or her explicit consent*
* *For the purposes of monitoring equality of opportunity*
* *In order to exercise a right or obligation conferred or imposed by law, such as revealing information about past convictions in order to protect children under the Children Act*
* *In connection with legal proceedings or to obtain legal advice*
* *For the exercise of the functions of a Government department, such as tax returns to the Inland Revenue and national insurance payments to the Contributions Agency or statistical returns to funding agencies*
* *To protect the individual’s interests where it is not possible to obtain the individual’s consent, or the University cannot reasonably have been expected to obtain the individual’s consent*
* *The individual has deliberately made the data public, for example by talking to the media or writing an article*
* *For medical purposes such as an examination carried out or a report written by a health professional.*
	+ 1. *Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any matter incompatible with that purpose or those purposes.*
		2. *Personal data shall be accurate and, where necessary, be kept up to date.*

*The University undertakes to maintain its files accurately and to ensure the information contained therein is up-to-date. In particular, it undertakes to carry out regular audits on the accuracy of data.*

* + 1. *Personal data processed for any purpose shall not be kept for longer than is necessary for that purpose.*

*The University will keep under review the length of time that information is held, and the purposes for which it is held. Where there is no legal requirement to retain personal data, the University reserves the right to de-personalise the data to prevent identification of particular individuals for historic, statistical or research purposes.*

* + 1. *Personal data shall be processed in accordance with the rights of data subjects.*

*The University will keep individuals informed about whether any data relating to an individual is being processed, what the data consist of, the purposes for which the data are being processed, and the recipient of the information. Employees will be informed about the logic in decision-making where processing by automatic means is the sole basis for any decision significantly affecting them; the University undertakes not to make decisions about recruitment, appraisal and promotion exclusively on the basis of automatic means such as computer software.*

* + 1. *The appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data.*

*The University undertakes to ensure security in respect of data, to ensure no unauthorised access either physically in to the computer premises or manual filing systems, or into the computer software.*

* + 1. *Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.*

*The University will not transfer any data without satisfying the standards required under the Act, which does place restrictions on where data may be sent. This will include data published on the University website.*

## SECURITY OF DATA

*Section 4 – Security of Data*

*To ensure that security is maintained in relation to the information that the University holds all staff must observe the following provisions:*

* *Access to personal data held on mainframe, personal and laptop computers, microfiches, compact disks, floppy disks and manual files must not be allowed to any person (whether or not that person is a member of staff of that or any other department) without the express permission of the relevant HoD (manual files includes cards and/or papers which are a ‘relevant filing system’).*
* *Personal data relating to staff, students or any other persons must not be entered into, amended or deleted from any mainframe, personal or laptop computer, microfiche, compact disk, floppy disk or manual file without the express prior authorisation or permission of the appropriate HoD or strictly in accordance with written procedures or instructions issued by him/her.*
* *Disclosure of any personal data held in any form must not be made to any person (whether or not that person is a member of staff of that or any other Department) without the express prior permission of the appropriate HoD.*
* *Members of staff must not seek to obtain by any means any personal data held by or on behalf of the University in any form except on a genuine ‘need to know’ basis or arising from their own duties and responsibilities.*
* *Wilful or negligent failure to observe these rules will be treated as a disciplinary matter and action may be taken under the University's Disciplinary Procedure.*

Ethics Committee

Date Approved: May 2014