Ethical Guidelines for Teaching and Research

University Ethics Committee

October 2009
Ethical Guidelines for Teaching and Research at the University of Surrey

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1. **INTRODUCTION**

In January 1973, the Senate set up a University Committee on Ethics, with the remit to draw up a set of Guidelines for areas of teaching or research within the University which involved considerations of an ethical nature.

In July 2003, the Senate approved a revision to the Title, Constitution and the current membership provision of the Committee (see Appendix I), and to the terms of reference.

In 2008, the Senate approved changes to the University Ethics Committee constitution to increase its membership and formally include the Deputy Chair and lay member. The revisions have also ensured that all relevant disciplines are covered thoroughly by staff expertise.

The Guidelines and Terms of Reference outlined in this booklet are those approved by the Senate on 2 May 1978, on 28 June 1988 and subsequently.

1.1 **Terms of Reference**

i) To consider general issues arising within the University which involve considerations of an ethical nature;

ii) To prepare guidelines in relation to ethical issues which may arise from teaching and research activities within the University;

iii) To be available for consultation on such ethical issues by the Senate or any other corporate body, and by individual members of staff or students of the University;

iv) To consider, and in appropriate cases grant a favourable ethical opinion, specific representations and research protocols submitted to it by members of staff and students of the University, or representatives of certain external bodies working in collaboration with members of the University;

v) To report on the exercise of the Committee’s functions, and make recommendations to the Senate as appropriate, through the Executive Board, on key matters of policy and strategy related to ethics.

2. **COMMITTEE PROCEDURE**

The University Ethics Committee meets three times a year, although research protocols requiring a favourable ethical opinion from the Committee are dealt with by correspondence on a continuous basis. Proposals are given a favourable ethical opinion (i.e. the terminology ‘approval' is not used) on the unanimous decision of the Committee members and not on a majority decision.

Special meetings of the Ethics Committee can be convened to resolve any issue in the event that any member expresses a major reservation about a particular proposal and that issue is not resolved by the investigator.

There are also three Faculty sub-committees – see 2.2.

2.1 **Submissions to the University Ethics Committee**

Submissions to the Committee for consideration and a favourable ethical opinion should be made in the first instance to the Secretary or Administrator of the Committee (See appendix II for contact details). The Committee will endeavour to deal with these expeditiously, but those submitting proposals are advised to allow 28 days.
Any experiment or procedure which falls within one or more of the following categories must be referred to the University Ethics Committee or the relevant sub-committee for consideration and ethical opinion:

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

b) surveys and questionnaires, the nature of which might be offensive, distressing or deeply personal for the particular target group;

c) proposals which involve financial payments or payments in kind to participants;

d) proposals wishing to use undergraduate students as participants;

e) research proposals to be carried out by persons unconnected with the University, but wishing to use staff and/or students as participants;

f) proposals which investigate existing working or professional practices at the researcher’s own place of work.

Investigators are also asked to note that research proposals involving any of the following MUST also be submitted to an NHS Research Ethics Committee for ethical review and favourable opinion before submission to the relevant University Ethics Committee, as research proposals which meet any of these criteria will not be considered until a favourable ethical opinion from the NHS REC, (or written confirmation that NHS opinion is not required), has been obtained.

a) patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user’s past or present treatment by, or use of, the NHS. It includes NHS patients treated under contract with private sector institutions.

b) individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above.

c) access to data, organs or other bodily material of past and present NHS patients.

d) fetal material and IVF involving NHS patients.

e) the recently dead in NHS premises.

f) the use of, or potential access to, NHS premises or facilities.

g) NHS staff – recruited as research participants by virtue of their professional role.

To submit your proposals for ethical opinion, you should complete the Ethics Committee’s Protocol Cover Sheet and the necessary accompanying documents listed on its checklist. This cover sheet and further guidance is available, on request, from the Committee Secretary, The Registry, or by downloading from the Committee’s website at http://portal.surrey.ac.uk/registry/ethics.
Researchers involved in preparing protocols for submission should be aware of certain other general considerations, including insurance cover, and the requirements and obligations of prevailing legislation, such as the Human Rights Act 1998 and the Data Protection Act 1998. Researchers are advised to refer to Section 4 of this document before submitting a proposal to the Committee.

2.2 **Faculty Ethics Committees**

Faculty Ethics Committees have been established for the following Faculties:

- Faculty of Arts & Human Sciences
- Faculty of Health & Medical Sciences
- Faculty of Management & Law

These Committees are sub-committees of the University Ethics Committee, and act in accordance with its published procedures and practices. The Faculty of Engineering & Physical Sciences has too few instances per year to warrant its own Ethics Committee; these protocols are sent to the main University Ethics Committee.

2.3 **Where to submit your protocol**

Faculty Committees review protocols submitted by Undergraduate and Postgraduate (Taught) students (except when the student recruits University of Surrey staff/students from outside their Faculty or when NHS approval is required).

The University Ethics Committee reviews protocols submitted by Postgraduate (Research) students, Faculty of Engineering & Physical Science students, staff and all other groups.

2.4 **Responsibilities**

Deans of Faculty/Heads of Department are responsible for teaching and research carried out within their own Faculty/Department and under the supervision of their own staff.

It is the responsibility of all supervisors to ensure that any students involved as researchers or in conducting experimentation are aware of the Ethical Guidelines and that the Ethical Guidelines are observed.

It is also the role of the supervisor to check the researcher’s documentation, correcting any inaccuracies including spelling and grammar, before signing it off for submission to the Committee.

2.5 **Translation of documents**

The Committee considers translated documents on a case-by-case basis where no official translation can be provided. On the whole, the Committee would accept the researcher’s own signed translation provided that it was accompanied by the original document, but this would be subject to consideration. Where applicable, the supervisor/Principal Investigator should also sign to agree the accuracy of the translation and this would be acceptable. The Committee might also request further information and evidence from the researcher if presented with a document in a foreign language.

2.6 **Research conducted outside of the UK**
Researchers are asked to reflect on the ethical practice in the country they are researching in. The responsibility for monitoring the researchers’ activities in relation to established practice and requirements lies with their supervisor (where applicable).

The Committee’s routine audit process might also pick up any inconsistencies with research conducted outside of the United Kingdom’s legislation.

2.7 Sponsor’s representative signatures and Sponsor letters

The University is a recognised research sponsor under the Department of Health’s Research Governance Framework.

If you are working with the NHS and require a signature from the sponsor’s representative, or a sponsorship letter, please approach the Secretary to the University Ethics Committee in the first instance. If the Secretary is absent, the Administrator to the Committee is able to provide the letter and/or signature. In the unlikely event that the Secretary and the Administrator are absent, the Chair of the Committee is able to ensure that these are provided.

This arrangement applies to all levels and types of research at the University, except trials with the Clinical Research Centre (CRC), where the Director of the CRC has delegated responsibility from the University to sign under the ‘sponsor’ section and to provide sponsorship letters.
3. THE GUIDELINES FOR RESEARCH INVOLVING HUMAN SUBJECTS

The following Guidelines are concerned with teaching and research involving human subjects. All teaching experiments and research carried out in, and by members of, the University of Surrey should conform with the “Universal Declaration of Human Rights and Covenants on Human Rights” (UN General Assembly, December 1984) and with the University’s Guidelines set out below. Researchers in the biological and human sciences are also required to observe the ethical guidelines advocated by their own appropriate Society or Professional Body, as laid down from time to time. Statements from certain of these Bodies are available, on request, from the Committee Secretary or can be found on the internet:

- Universal Declaration of Human Rights and the Covenants on Human Rights;
- The British Sociological Association – Statement of Ethical Practice; (http://www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm)
- The British Psychological Society – Code of Conduct, Ethical Principles and Guidelines; (http://www.bps.org.uk/the-society/code-of-conduct/)
- The Ergonomics Society – Code of professional conduct for registered members, fellows and registered consultancies; (http://www.ergonomics.org.uk)
- Medical Research Council – Good Practice Guide/Principles in the assessment and conduct of medical research and publicising results; (http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002415)
- The Social Research Association – Ethical Guidelines; (http://www.thesra.org.uk/ethical.htm)

Experimentation in morbid anatomy and on animals is strictly controlled by licence and falls outside the scope of these Guidelines (see Sections 4.7 and 4.8).

3.1 Hazards to health which might be occasioned by medical/clinical trials, eg. all drugs trials and the administration of drugs and other substances in pharmacological doses for research purposes.

(a) A signed statement from all participants shall be required certifying their real informed consent to the experimentation.

(b) The participant has the right to withdraw from the experimentation at any stage and it is the responsibility of the researcher to make this understood in advance of the study.

(c) For any participant on a drug or clinical trial, it is the responsibility of the project supervisor to contact the General Practitioners of the participants to confirm their suitability for inclusion in the trial prior to its commencement.

(d) Arrangements shall be made by the investigators for all participants engaging in medical/clinical trials to be medically screened before the trials begin.

(e) The administration of drugs shall be carried out under the supervision of a registered Medical Practitioner.
(f) Participants for drug trials/bioavailability testing shall not normally be undergraduate students.

(g) In the case of undergraduates or other participants, nobody under the age of 18 shall be allowed to participate without written parental consent.

(h) The Dean of Faculty/Head of Department shall have the right to object where there is substantial interference with the work of the Faculty/Department caused either directly or indirectly through loss of time and/or efficiency of the participant.

(i) In the case of a student or technician participant, a formal obligation shall rest with the researcher to notify the Dean of Faculty/Head of Department of each participant concerned.

(j) Where an investigation requires the identification of a particular patient group within the University, individuals shall be contacted in the first instance through the Student Medical Officer.

(k) It is permissible for any member of the University to display notices calling for participants to 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 shall aim to give details about the level of commitment involved.

(l) Full information on official Faculty/Departmental headed paper shall be made available to prospective participants soon after the initial call for participants to a particular study.

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

(n) In cases where a proposal, necessitating the administration or trial of drugs to or on participants involves financial inducement to the subjects, details relating to the amount of financial inducement and the nature of the drug (in accordance with (m) above) shall be notified to the Ethics Committee at the time of submission.

(o) Approval for the use of an untried drug produced by a commercial company shall be referred in the first instance to the Medicines and Healthcare Products Regulatory Agency (MHRA) and written evidence of approval shall be obtained and submitted to the Ethics Committee. If an individual (with medical supervision) intends to try ‘substance X’ which has been isolated, MHRA approval is not required.

(p) In all cases a letter shall be sought from the Drug Company concerned giving complete and accurate information concerning the trial in relation to its responsibility for any malconsequences (see the note on Insurance, Section 4.1).

(q) If there are any doubts about whether the experimentation involves risk of an abnormal nature (i.e. abnormal in relation to the usual type of experiments carried out by the University), it is the responsibility of the researcher concerned to contact Business Support Services (extension 9008) to confirm or arrange insurance cover for the University (see also the note on Insurance, Section 4.1).
(r) The Committee must be informed and consulted if any significant material change is made to a protocol that has already been given a favourable ethical opinion.

(s) Any significant untoward event occurring during or as a result of a study affecting a participant shall be communicated promptly to the participant’s General Practitioner/Student Medical Officer and be drawn to the attention of the Ethics Committee.

**Studies involving blood sampling or the handling of blood and other human specimens must be carried out in accordance with the University’s Policy on the Donation and Use of Human Specimens in Teaching and Research (SP/03/98). Please contact the Committee Secretary for a copy of the policy.**

### 3.2 Hazards to health which might be occasioned by physiological experiments and measurements involving the inducement of more than minimal stress by isolation, fasting, sleep deprivation, noise, exercise, exposure, submersion, electronic and/or other means.

In most instances, the Guidelines for medical/clinical trials should also be used to cover hazards to health occasioned by physiological experiments and measurements, except that, additionally:

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

b) The Ethics Committee may require that such experimentation be supervised by a registered Medical Practitioner.

c) In cases where a proposal involves financial inducements to the subject, details relating to the amount of financial inducement shall be notified to the Ethics Committee at the time of submission.

### 3.3 Teaching Experiments

i) The Ethics Committee considers that it is ethically acceptable to request an undergraduate or postgraduate student to participate in physiological experiments (e.g. swallowing a naso-gastric tube or using an exercise bicycle), or in experiments in the behavioural sciences as a normal part of his/her programme on the understanding:

a) that the supervisor ensures that all such studies conform with the Committee’s Guidelines;

b) that the student has the right to decline a particular procedure on religious, physiological grounds etc;

c) that the student must be assured that, by declining to participate in a particular procedure, his/her marks will NOT be adversely affected;

d) that undue academic pressure or financial inducement shall not be brought to bear on the student;
e) that the policy and procedures be observed (Section 3.4 refers) relating to students undertaking tests as a routine part of a programme of teaching or research, from which unexpected results with possible health implications for the participants/participants might arise;

f) that it is the responsibility of the members of staff conducting the experiment to take reasonable steps to ascertain that the student is in good health and knows of no reason why he/she should not participate.

Teaching experiments and research procedures involving blood sampling or the handling of blood and other human specimens must be carried out in accordance with the University’s Policy on the Donation and Use of Human Specimens in Teaching and Research (SP/03/98).

ii) The Use of Animal Tissues

The understanding of animal metabolism and physiology is not complete without some studies on animal tissues. Thus students in the biological sciences should expect to be involved in such studies.

Nevertheless any student may decide that they do not wish to participate in any particular animal experiment, and this is acceptable provided that they inform the member of staff responsible for that practical in advance. Normally the student will then receive an alternative piece of coursework.

3.4 Policy and procedures relating to students undertaking tests as a routine part of a programme of teaching or research, from which unexpected results with possible health implications might arise.

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 shall be included in writing or displayed:

“Students will be asked to participate on the understanding that:

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

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

c) neither declining nor accepting to participate shall affect the assessment of work in any way;

d) the student is in good health and knows of no reason why he/she should not participate”;

In the event of untoward results being obtained, the following may be helpful:

ii) Where the supervisor alone is the investigator, he/she should:
a) advise the subject that there are wide variations between individuals;
b) indicate that it is possible that, however unusual a result may be at first
sight, there may be several well-documented anomalies;
c) avoid the concept of ‘normal/abnormal’, but rather employ the concept
of ‘a range of reference values’;
d) cite, for example, the case of red hair – i.e. red hair is unusual in
Caucasian races, but not unhealthy;
e) resist any attempt to interpret the results within the Faculty/Department,
particularly in terms of medical significance or diagnosis;
f) advise the subject to consult the Student Medical Officer in confidence in
the first instance. It will be the responsibility of the subject to take or
disregard the advice.

iii) Where a student is acting as the investigator:

a) the procedures set out in Section 3.4 i) above should be explained to the
student by the academic supervisor, including the requirement by any
investigator to treat any results with the strictest confidence;

b) where an untoward result is obtained, the investigator should report the
matter as soon as possible to his/her academic supervisor, who will then
take appropriate action.

3.5 The use of questionnaires and testing within and outside the University.

Note

The words ‘questionnaire’ and ‘testing’ are used here on the presumption 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.

When the questionnaire is of a potentially offensive, distressing or deeply
personal nature, or when there are special reasons why any of the guidelines
outlined below are not observed, a copy of the questionnaire shall be submitted
to the Ethics Committee for discussion and recommendation. Other
questionnaires need not, of necessity, be submitted to the Committee for ethical
opinion, provided that the following guidelines are observed:-

a) The purpose of the questionnaire or test shall be clearly defined by the tester
or researcher who has a responsibility to explain to the subjects as fully as
possible (i.e. without prejudicing the objectives of the study) what the
research is about, who is undertaking and financing it, and why it is being
undertaken.

b) When the subject is a student, the questioner or tester shall inform the
student if completion of the questionnaire or attendance at a test is an
obligatory part of the student’s programme, or will in any way contribute
towards the student’s final assessment.

c) The manner in which the questionnaire is presented shall give the recipient
the right not to participate.
d) Notwithstanding the agreement of a subject to participate in any questionnaire, survey or testing covered by the guidelines above, he or she may, at any stage, withdraw that agreement.

e) The information from any individual questionnaire shall remain confidential, and the anonymity of respondents shall be preserved.

f) In all cases where there occurs either a deliberate or accidental breach of confidentiality, the individual conducting the survey or testing shall be held responsible.

g) Publishing or divulging information to another person, Faculty/Department or researcher from which individual identity may be deduced shall be only with the written consent of the individuals concerned immediately prior to publication.

h) Any researcher processing personal data shall be aware of and comply with the provisions of the Data Protection Act, 1998. The Committee’s sample consent form includes a paragraph on the Data Protection Act which can be amended as required by the researcher.

i) It is permissible for a research worker, member of staff or other member of the University to display notices calling for participants to answer questionnaires or participate in any form of research, subject to the normal courtesies and rules governing the use of notice boards, pigeon-holes and circulation systems. These notices shall aim to give details about the level of commitment involved.

j) A student or other member of the University shall be free to participate in any form of questionnaire, survey, research or service testing, except during hours specifically timetabled for academic purposes, when the prior consent of the member of staff concerned shall be sought by the person conducting the enquiry.

k) As a matter of courtesy, any undertaking given to participants by the investigator or tester shall be honoured, even if the information gathered may not be used subsequently. For example, if householders are told that completed questionnaires will be collected, then arrangements shall be made to do this.

4. GENERAL CONSIDERATIONS

4.1 Insurance

a) The University holds two types of insurance to cover claims arising from its involvement in clinical trials: liability (Public Liability) and no-fault (Clinical Trials). The liability policies cover the University’s legal liability to third parties, including subjects and sponsors. The no-fault policy is intended to provide compensation to subjects, regardless of liability, in the event of their suffering a significant and enduring injury (including illness or disease) which, on the balance of probabilities, is directly attributable to their involvement in the trial.

b) The Public Liability policy covers harms to individuals which arise from their participation in a clinical trial where the University is shown to be liable. The limit of indemnity under this policy is £35m per claim, with no annual aggregate limit.
c) This policy carries an endorsement which means that it does not cover legal liability arising from actual drug studies, nor those requiring non-fault compensation cover. Cover for these types of studies is provided under a separate Clinical Trials extension. It carries a limit of indemnity of £10m per trial, £12.5m in aggregate per annum.

d) Any clinical research requiring a Clinical Trials authorisation from the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004 is classified as a Clinical Trial. (please see Is it a ClinicalTrial: http://portal.surrey.ac.uk/policies/bsp/insurance/Is%20it%20a%20Clinical%20Trial.pdf)

It has been agreed with the University’s insurers that the subject’s GP will be contacted regarding their suitability for inclusion in a drug trial and for any other clinical trials where the subject’s health and medical record is relevant.

e) **Cover for clinical trials excludes the following five:**

- Subjects who are known to be pregnant at the time of the trial
- Subjects who are under 5 years of age at the time of the trial
- Any trial in which the medicinal purpose is to either assist with, or alter, the process of conception, or investigating or participating in methods of contraception
- Any trial involving genetic engineering other than one where the medical purpose is treating or diagnosing disease
- Any trial where the substance under investigation has been designed and/or manufactured by the University.

f) In addition, insurers expect drug trials to be conducted in accordance with the Association of British Pharmaceutical Industry Guidelines. This means that where the trial is sponsored by a pharmaceutical company, that company should issue the standard ABPI form of indemnity and offer no-fault compensation.

g) Claims from sponsors for the University’s negligence in the conduct of a study is covered under the Professional Negligence policy. This carries a limit of indemnity of £7.5m per claim and in aggregate.

h) The policies do not cover medical and dental practitioners while working in a professional capacity. It is the responsibility of the individuals concerned to obtain insurance in their own name through an appropriate medical defence organisation. Nurses are covered under the University’s policies, provided that they are assisting in a trial being undertaken at the University itself, and provided that they only undertake activities which fall within the scope of duties normally expected of nurses. It is assumed that they will have RCN membership.

i) For insurance purposes, it is essential that students acting as investigators are supervised by an employee of the University.

### 4.2 Ethical opinion from collaborating organisations

Research protocols which involve access to subjects under the day to day care of a hospital or clinic will need to produce evidence that the investigator has the
agreement of the appropriate Ethical Committee governing the hospital(s) or clinic(s) concerned. Similarly, protocols which use hospital or clinical premises, other than those which are available within the University, will normally need to produce such evidence.

4.3 Proposals for ethical opinion from Associated Institutions

The Ethics Committee is prepared to consider and grant an ethical opinion to 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 undergraduate or postgraduate programmes which are validated by the University of Surrey. In these circumstances, the Ethics Committee (or representative thereof) reserves the right to inspect the appropriate premises and facilities within the institution.

4.4 Researchers from outside the University seeking to use University students and/or staff as participants

a) Researchers from, and research proposals generated outside the University, but wishing to use University students and/or staff as participants, must first seek an academic ‘assessor’ from within the University, who is independent of the sponsors. The ‘assessor’ shall not be liable for any malconsequences arising from the research, but shall be responsible for ensuring that the proposal falls within the provisions of the Guidelines.

b) All proposals by an external sponsor wishing to use students and/or staff as participants must be submitted to the Ethics Committee for ethical review. All such proposals shall be accompanied by a statement from the sponsors accepting full responsibility for any malconsequences.

c) In the interests of the students concerned, the names of any students participating in projects involving medical or psychological experimentation (see also Sections 3.1 and 3.2 of the Guidelines) undertaken by researchers from outside the University, whether those projects are externally or University-based, shall be submitted to the Student Medical Officer. This information will be subject to the usual requirements for the preservation of medical confidentiality.

4.5 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 primarily commercial and/or 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, relevant details of that contract/project shall be notified to the Ethics Committee and shall include details of the amount of financial inducement concerned, the nature of the contract and the medicine or appliance to be evaluated.

4.6 Personal payments to investigators, Faculties/Departments and institutions

Personal payments received by investigators, and their pecuniary relationship with any sponsoring company have ethical implications.
Details of specific payments to investigators, Faculties/Departments or institutions shall be reported to the Ethics Committee when submitting a protocol. This information will be treated in confidence.

Investigators who receive payment as part of an annual consultancy fee shall advise the Committee of this situation, but further details of such payments will not normally need to be declared.

4.7 **Experimentation on animals**

Experimentation on animals is strictly controlled by Home Office licence, and falls outside the scope of these Guidelines. It may, however, be helpful to know that certain of the Departments/Units of the University are registered by the Home Secretary as places where animal experiments, regulated by the Animals (Scientific Procedures) Act 1986, can be carried out. Such experiments may be carried out only by individuals holding a licence granted personally to them by the Home Secretary for experimental procedures approved under a specific project licence granted usually only to senior members of staff. A fee is payable in respect of both personal and project licences.

Registered premises are visited at frequent intervals, without warning, by an Inspector from the Home Office, and the laboratory authorities and licence holders are required to co-operate with the Home Office in ensuring the strict observance within the registered premises of all provisions of the Act; failure to comply could lead to withdrawal of the licence or cancellation of registration. All projects must be overseen by a designated, registered veterinary surgeon whose decisions on all matters of animal health are final.

Anyone who believes that they need to conduct experiments on animals genuinely to further scientific knowledge should read the Animals (Scientific Procedures) Act 1986 and satisfy themselves that the proposed experimentation and procedures are both legal and ethical. An approach can then be made to the most appropriate authorised project licence holder in the University to seek his or her permission to supplicate to the Home Office for a personal licence to undertake the work proposed, providing it falls within the terms of the specific project licence.

4.8 **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.

4.9 **Data Protection Act, 1998**

The Act governs the collection, retention, use and disposal of personal data where a computer and/or structured manual filing system is involved, and makes it an offence to store or process personal data except in strict accordance with the terms of the University’s annual Notification to the Information Commissioner (formerly the Data Protection Registrar).

The University is an authorised data controller. All staff and students are specifically advised:

i) that the University does not authorise any of its employees or agents to hold or process any personal data on its behalf except as stated in the University’s annual Notification made pursuant to the Data Protection Act;
ii) that students must not hold or process any personal data for use in connection with their academic studies or research without the express authority of their tutor or supervisor;

iii) that tutors and supervisors who give permission to their students to hold or process personal data are themselves responsible for ensuring that the activity complies with the University’s annual Notification, the Data Protection Principles and any Data Protection Policy it has issued.

Consent forms should contain a paragraph regarding data protection; however the researcher is able to amend this as appropriate. The standard form of wording is:

I consent to my personal data, as outlined in the accompanying information sheet, being used for this study and other research. I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998).

If the Researcher requires consent for the data to be used on a wider basis then the consent could be extended to "and interested parties". However the Researcher should be explicit in who could have access to the data.

A copy of the details of the University’s annual Notification may be inspected on application to the University’s Data Protection Officer (Business Support Services) who should be consulted in cases of doubt or difficulty.

July 2003
Minor amendments: January 2010
APPENDIX I

Constitution of the University Ethics Committee

**Chair** - To be appointed for a period of three years by the Senate on the nomination of the Vice-Chancellor.

**Deputy Chair** – to be agreed by the Committee from amongst its members and reviewed on an annual basis.

**Co-opted** - Up to three members, at least one of whom should be medically qualified, and one of whom should be a lay person from outside of the University.

**Nominated** – Up to three members from each Faculty to represent the following areas of each Faculty:

- **Faculty of Arts & Human Sciences**: Psychology and Sociology
- **Faculty of Engineering & Physical Sciences**: Engineering and Physical Sciences
- **Faculty of Health & Medical Sciences**: Health & Social Care, Biomedical & Molecular Sciences, Postgraduate Medical School
- **Faculty of Management & Law**: Management and Law

**In Attendance** – Secretary

All Members should be appointed for a period of two years.
Appendix II

Guidelines For The Preparation Of A Submission To The University's Ethics Committee For Ethical Review of A Study

The following text is also supplied as a separate document on the Ethics Committee webpages at [http://portal.surrey.ac.uk/registry/ethics/submission](http://portal.surrey.ac.uk/registry/ethics/submission)

**General Instructions**

1. All investigators should read the *University of Surrey Ethical Guidelines for Teaching and Research* before submitting a proposal to the Committee, and where appropriate, refer to the *Policy and Guidance Notes on the Donation and Use of Human Specimens in Teaching and Research in the University of Surrey* for all trials involving blood or other human specimens. Researchers undertaking clinical trials should also refer to the *EU Directive on Good Clinical Practice in the Conduct of Clinical Trials* and ensure that their protocol complies with *The Medicines for Human Use (Clinical Trials) Regulations* which were implemented on 01 May 2004.

2. The *Protocol Cover Sheet* should be completed and returned with your detailed protocol, and all other relevant documents, to the Secretary of the Ethics Committee. No action in respect of facilities and dates should be taken until the Committee has confirmed a favourable ethical opinion.

3. The letter confirming favourable ethical opinion relates to your specified research protocol; the Committee should be notified of any changes to the proposal, any adverse reactions, or if the study is to be repeated using a different group of research participants. The Committee should also be advised when your research project has been completed.

**How to complete the Protocol Cover Sheet**

1. **All** sections should be completed; any sections not appropriate to your submission should be identified by 'N/A'.

2. Section 2 should contain the names of all those directly concerned with the study. All those named **must** sign the final section of the form. **N.B.** Submissions from researchers who are registered as students of the University **must** include their supervisor as a Principal Investigator.

3. Section 3 must contain the signature of the supervisor, where appropriate, to indicate that (s)he has read and approved the protocol submission, including for proofreading and accuracy. Where the Committee raises queries on a protocol, the researcher should consult their supervisor where necessary to ensure that their response to the Committee is accurate.
4. Section 4 should contain the names of those who make other contributions to the study, e.g. statisticians, analysts, phlebotomists. Where collaborators have direct contact with the volunteer subjects, such as the phlebotomist, the agreement of the collaborator to perform the task must be provided in writing.

5. In sections 5, 6, 8 and 11 please do not write ‘N/A’, but ‘none’ might be an acceptable response. The answers to these questions may have important ethical implications and therefore they should be answered fully. Proposers should note that all information submitted to the Committee is treated as confidential.

6. Section 12 should contain information relating to applications to/favourable ethical opinion from NHS Research Ethics Committees in cases where the research meets the specified criteria.

7. Section 13 should provide details of any risk assessments that have been carried out in relation to the research project, either for potential participants or the researchers themselves. A risk assessment is simply an examination and written statement of the potential hazards (anything that can cause harm) and risks (chance, high or low that someone will be harmed by the hazard) associated with the research, their significance and the measures which have been put in place to minimise or control them.

8. Section 16 should provide information relating to the arrangements for collection, retention, use and disposal of research data, including measures to ensure the confidentiality of personal data.

Accompanying Documents

All submissions should include the following documents:

- **A summary of the project, including its principal aims and objectives**
- **A detailed protocol for the project**
- **An Information Sheet for participants**
- **A copy of the Consent Form for participants**
- **A completed Protocol Submission Pro-Forma: Insurance**

In instances where a proposal has received the prior agreement of another Research Ethics Committee (i.e. an NHS committee), the University Committee will accept the submission in the form of a completed Protocol Cover Sheet, together with the documentation submitted to the REC, and written confirmation of their favourable ethical opinion.

Documents on the checklist

The following points are intended as a guide to the type of information required in the Accompanying Documents specified in the checklist on the Protocol Cover Sheet.

**A summary of the project**

This should be approximately 500 words about the project, written in ‘lay terms’ (simple language which is able to be understood by the average individual or someone without
A detailed protocol for the project should include:

- a brief background to the study;
- the objectives of the study; the hypothesis to be tested;
- criteria for the selection of participants - inclusion and exclusion criteria;
- the number of participants to be recruited;
- experimental design and the methods to be used (NB: a summary table is very helpful where participants are to undergo a variety of treatments or tests over a period of time);
- study evaluation and statistical analysis;

Information Sheet for participants should include:

- a brief description of the project, in a form that can be understood by participants;
- the use or potential benefits of the study;
- whether the GPs of the participants will be contacted to confirm their suitability for the study, (a copy of the proposed letter to the GP should be included in the submission).
- the obligations and commitments of the participant during the study;
- the rights of the participant - the right to withdraw from the study without having to give a reason and confidentiality of all identifiable information and data;
- any expenses or payments to be made and any conditions attached to these;
- a short statement providing information on who participants can contact if they have a complaint or concerns about the study. Suggested wording: "Any complaint or concerns about any aspects of the way you have been dealt with during the course of the study will be addressed; please contact [insert name of Principal Investigator], Principal Investigator on [insert contact number]."

Consent Form for participants should include:

- acknowledgement that:
  - a full explanation of the project has been received;
  - all questions have been answered;
  - all advice, information and instructions have been understood;
- agreement to:
  - take part in the study voluntarily;
  - comply with the instructions and co-operate fully;
  - contact being made with the participant’s GP;
  - data being kept under the Data Protection Act (or however the researcher intends to use it – this should be stated clearly)
- a record of:
  - the rights of the participant;
  - the agreement concerning any payments or expenses;

The Consent Form should carry the names of the investigator, the participant and a witness (where appropriate), all of whom should sign and date the form; a copy should be given to the participant. It is suggested that this form should be the only document to contain the name of the participant. In all subsequent records, data and documents, the participant should be identified only by a code number to provide confidentiality. The Consent Form and code should be held in a secure place.
Protocol Submission Pro-Forma: Insurance

Please refer to Insurance Guidelines before completing this form. All sections should be completed; sections not appropriate to your submission should be identified by ‘N/A’. For any queries relating to Insurance, please contact Business Support on extension 9008.

Questionnaires and Interviews

The complete questionnaire must be submitted to the Committee. Where information is to be obtained by interview, details of the line of questioning should be provided. Any advertisements or questionnaires themselves should contain a line stating ‘This study has received a favourable ethical opinion from the University of Surrey Ethics Committee’.

Correspondence related to the project after it has been granted a favourable ethical opinion

All correspondence should be on University stationery, and should clearly state the title of the project and the name of the participating University Faculty/Department. Replies should be directed to an address within the University. Exceptionally, where a project is being conducted at another institution, e.g. as part of a PhD collaborative programme, the stationery of an external institution is acceptable. In either case, requests for replies to be sent to private addresses are not advised.

Examples of such correspondence are:
- requests for collaboration with professional bodies or individuals
- requests for assistance in locating suitable participants
- requests for assistance in the completion of questionnaires
- letters to participants’ GPs
- general correspondence with participants

Proposers are advised to submit specimen letters to the Committee. NB: If the project includes distribution of a survey or questionnaire to members of the University community, researchers are asked to include a statement advising that the project has been reviewed by the University’s Ethics Committee. Suggested wording: ‘This project has been given a favourable ethical opinion by the University of Surrey Ethics Committee’.

Submitting your protocol

One hard copy of the protocol cover sheet and accompanying documents should be sent to the Ethics Committee administrator in Registry. Please ensure that appropriate signatures are obtained and that the original copy is submitted. The Committee works on a continuous correspondence basis and therefore there are no dates by which protocols should be submitted.
**CONTACTS**

If applicants require further information or advice about making a submission to the Committee, they should contact:

The Administrator to the Ethics Committee, Ms Susan Douthwaite, Tel: (01483) 682051, email: s.douthwaite@surrey.ac.uk

Or the Secretary to the Ethics Committee, Mr Glenn Moulton, Tel: (01483) 689425, Email: g.moulton@surrey.ac.uk.

For enquiries relating to **insurance** or **indemnity** for your research, please contact Ms Nicky Routh, Tel: (01483) 689008, or email n.routh@surrey.ac.uk.