Ethical Principles & Procedures for Teaching and Research

University Ethics Committee (UEC)

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Ethical Principles & Procedures for Teaching and Research at the University of Surrey

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1. INTRODUCTION

The University exists to advance and disseminate knowledge and learning while maintaining proper ethical standards. Therefore, in January 1973, the Senate set up a University Ethics Committee (UEC) with the remit to draw up a set of Principles and Procedures for teaching and 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 membership provision of the Committee (see Appendix I), and to the terms of reference. Further revisions in 2008 and 2010 increased the membership and also ensured that all relevant disciplines are covered thoroughly by staff expertise.

The Ethical Principles and Procedures 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 Purpose

The purpose of these principles and procedures is to support staff in their consideration of ethical issues arising from academic activity, in accordance with certain general principles and standards approved by the University. Although the decision to undertake an academic activity such as research rests with the individual member of staff, such decisions must be taken within the broader ethical framework of the University, and it is the responsibility of the individual to seek guidance on and, if necessary, approval for activities which might be ethically sensitive.

The ethical standards which apply to academic activities (including research, teaching, consultancy and outreach work) arise from the basic principle that such activities should neither include practices which directly impose a risk of serious harm nor be indirectly dependent upon such practices. Serious harms include, for example, failure to respect the interests of human beings and damage to items of cultural value or the natural environment. Ethical practice also requires that the use of animals in academic work is fully justified and that statutory controls and codes of practice are observed at all times.

All activities undertaken by staff and students as members of the University must comply with the University's ethical standards. A flow diagram of the ethical approval process is attached (Appendix II) and staff and students should familiarise themselves with this process.

1.2 University Ethics Committee Terms of Reference

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

ii) To prepare a set of principles and procedures 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 of, 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 on key matters of policy and strategy related to ethics.

vi) To ensure research is carried out in accordance with the University's research values as outlined below.

1.3 Research Values

The University Ethics Committee recognises and endorses the concordat to support research integrity as published by Universities UK. The University Ethics Committee is committed to maintaining the highest standards of rigour and integrity in all aspects of research. The core elements of this are:

Honesty - 'in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings'

Rigour - 'in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results'.

Transparency and open communication - 'in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.' and

Care and respect - 'for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations'.

1.4 National and International References

These ethical principles and procedures are concerned with teaching and research involving human subjects. Experimentation in morbid anatomy and on animals is strictly controlled by licence and falls outside the scope of these ethical principles and procedures. 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 ethical principles and procedures set out below. Researchers in the biological and human sciences are also required to observe the ethical principles and procedures advocated by their own appropriate Society or Professional Body, as laid down from time to time. Statements from these Bodies are available, on request, from the Committee Secretary or can be found on the internet.

Useful links:

- Universal Declaration of Human Rights and the Covenants on Human Rights;
- The British Sociological Association – Statement of Ethical Practice;
- The British Psychological Society – Code of Conduct, Ethical Principles and Guidelines;
- The Ergonomics Society – Code of professional conduct for registered members, fellows and registered consultancies;
- Medical Research Council – Good Research Practice: Principles and Guidelines in the assessment and conduct of medical research and publicising results;
- The Social Research Association – Ethical Guidelines;

2. COMMITTEE PROCEDURE

The UEC 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 a subset 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 Faculty Ethics Committees (FEC) which deal with protocols submitted by undergraduate and postgraduate taught students – see 2.2.

To submit your proposals for ethical review to the University's Ethics Committee (where required according to the criteria listed in 2.1), you should complete the Ethics Application Form and the necessary accompanying documents listed on its checklist. This form and further guidance are available, on request, from the Research Integrity and Governance Office (RIGO) or from the Research Ethics webpages. The Committee will endeavour to deal with applications expeditiously, but those submitting proposals are advised to allow 28 days.

2.1 Criteria for ethical review

All research involving human participants should be evaluated against the criteria listed below for review by the University Ethics Committee (UEC) or Faculty Ethics Committee (FEC) (see section 2.2 'where to submit your protocol') before recruitment of study participants begins. Where the criteria for NHS review, full review or proportionate review apply, a favourable ethical opinion (FEO) from the relevant Ethics Committee must be received before the recruitment commences. Where research on human participants does not require NHS review or review by an Ethics Committee at the University a self-assessment form should be submitted online following the instruction on Research Ethics webpages before recruitment commences.

All researchers 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. It is the researcher's responsibility to ensure they obtain any additional ethical, legal or other approvals. These approvals can be NHS Research & Development (R & D) approval, approval from institutions hosting the research and/or approval from local organisations or gatekeepers. The need for additional permissions should also be considered if the research is being conducted (in collaboration with others) outside the UK (see section 2.5).

If changes are required by external bodies or the researcher decides to make changes to the submitted project, following a FEO, these changes should be referred back to an Ethics Committee as an amendment. The amendment should not be implemented before the appropriate confirmation of receipt or new FEO has been obtained. Further information, guidance and templates related to any of the ethics processes can be found on the Research Ethics webpages. If in doubt, please contact the RIGO.

A few notes for clarification:

- The term 'participant' should be taken to include any members of the research team or colleagues who volunteer to be subjects of the research.
- Any pilot studies that require the participant(s) to take part in a procedure that qualifies for review should be submitted for the relevant review. Studies that merely assess the feasibility of implementing a project do not need to be reviewed.
- Service evaluations, clinical audits, surveillance and usual practice, as well as studies involving NHS staff as defined by the HRA may need to be considered for ethical review according to the same categorisation below.
- Research should be reviewed on a project basis. An FEO is normally given for an individual project rather than a general procedure or research method. However, a project may be submitted either as an overall proposal or in different phases or stages as long as all activities that will be carried out are covered by an FEO.

2.1.1 NHS Review

Review by an NHS Research Ethics Committee (REC) is required for certain research projects, for example, but not limited to, studies that involve NHS patient groups, characterised by a specific disease or disorder, or their carers, adults lacking capacity to consent for themselves, investigational medicinal products/devices and ionising radiation. Please consult the HRA website for more information on legal and policy requirements for REC review or legal requirements only.

If you are required to submit to an NHS REC and/or an NHS R&D department you may want the University to act as Sponsor for the research. The University is a recognised research sponsor under the Department of Health's Research Governance Framework. In order to gain agreement that the University will sponsor your research you will need to follow the procedure outlined on the Research Ethics webpages which involves sending a pdf of a completed draft Integrated Research Application System (IRAS) form, along with all accompanying documentation to the RIGO. This documentation will be reviewed and if necessary, forwarded to the legal and insurance teams to ensure there is no reason why the University cannot sponsor your research. You will receive feedback on whether your proposal can be submitted to an NHS REC and/or NHS R&D department. If your research requires legal contracts then these need to be completed prior to the start of your project. This

arrangement for approving sponsorship applies to all levels and types of research at the University, except trials conducted by or in collaboration with the Clinical Research Centre (CRC), where an authorised member of staff at the CRC has delegated responsibility from the University and may sign under the 'sponsor' section and provide sponsorship letters.

Research projects which have received an FEO from an NHS REC do not need to be submitted to the UEC/FEC. However, for such projects, whether they are sponsored by the University or an external organisation, a notification including the NHS REC FEO will need to be sent to the RIGO. The RIGO will inform the researcher which additional documentation needs to be recorded for your study and will provide confirmation of Sponsorship for those studies sponsored by the University.

Once received, an on-going favourable ethical opinion from the NHS is subject to any conditions outlined in the FEO and accompanying condition letter, including supplying Annual Progress Reports and a Declaration of the End of Study to the NHS REC which gave the FEO. A copy should also be sent to the RIGO.

2.1.2 Full UEC review (only if none of the study procedures qualify for NHS Review)

Full UEC review is required for projects meeting one or more of the following criteria:

a) Projects that involve the inducement of more than minimal stress such as:
    i. procedures involving any risk to a participant's health or well-being (for example intrusive physiological or psychological procedures).
    ii. surveys, questionnaires and any research, the nature of which might be offensive, distressing or deeply personal for the particular target group, even if individuals are not identifiable. This may include questions on sensitive data, i.e. ethnicity, political views, religion, physical or mental health/condition, sexual life/orientation and alleged offences.

b) Proposals wishing to study children under the age of 16 or adults who may feel under pressure to take part due to their connection with the researcher.[2]

c) Research involving prisoners and young offenders.[3]

d) Research involving the new collection or donation of human tissue from a living person or the recently deceased according to the Human Tissue Authority.

e) Research involving previously collected human tissue or other data needs NHS or UEC review where:
    i. Consent for research (rather than or in addition to, for example, diagnostic purposes) has not been given, or the research is not within the terms of the consent (e.g. different types of analyses are carried out or for different aims than the participant initially gave consent for).

ii. The samples will be held on premises in England, Wales or Northern Ireland without a licence from the Human Tissue Authority to store relevant material for scheduled purposes (the University of Surrey does have this licence, for further information see the University's HTA pages).

iii. The research also involves removal, storage or use of new samples from the living or the deceased.

iv. The research involves use of identifiable information provided/held with the samples/data. This also holds for samples/data that are not anonymised in a sufficiently robust way which might allow the researcher or others to identify whom the sample was obtained from.

f) Research involving collection of or access to records of personal confidential data, concerning identifiable individuals as defined by the UK Data Protection Act 1998. These personal data include but are not limited to sensitive personal data (see a.ii) as well as academic & career information and some protected characteristics according to the Equality Act 2010, e.g. disability, marriage and pregnancy.

g) Studies that link or share personal data or confidential information beyond the initial consent given (including linked data gathered outside of the UK), for example where the research topic or data-gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

h) Research involving collection of or access to audio/video recordings, photographs, and/or quotations within which participants are identifiable, if these are to be disseminated beyond the research team. This will include publicly available information for example on social media and participants recruited or identified through the internet, if the understanding of privacy in these settings is contentious, where sensitive issues are discussed, or where visual images are used.

i) Proposals which require participants to take part in the study without their knowledge and/or consent at the time (e.g. covert observation, emergency research).

j) Research which involves deception other than withholding information about the aims of the research until the debriefing.

k) Proposals which involve financial payments or payments in kind to participants above reimbursement for out of pocket expenses, provision of refreshments or entry into a low-value prize draw or where the compensation could amount to more than the minimum hourly wage or £100 in total (whichever is higher), or proposals which otherwise offer incentives which may unduly influence participants' decision to participate

l) Research where the safety or well-being of the researcher may be in question.

m) Research where for any other reason the researcher feels significant ethical concerns may arise, or where an external funding body or sponsor requires full ethical review to be undertaken.

[2] For more information on working with children and young people, please see the HRA webpages about informed consent. Please note that you may need DBS clearance for working with anyone under 18 years of age even though those 16 and over are usually considered capable of consenting for themselves.

[3] For the various approvals required for working with prisoners or young offenders please see guidance from The Offender Health Research Network.

[4] It is assumed that in all cases researchers adhere to the relevant University of Surrey Health & Safety policies and other local procedures e.g. for lone working.

2.1.3 Proportionate UEC review

Proportionate UEC review is required for projects where none of the criteria for NHS or full review apply but the project meets one or more of the following criteria:

a) Physiological experiments and measurements that **do not** involve the inducement of more than minimal stress but which may incidentally lead to discovery of ill health in a participant.

b) Behavioural interventions and measurements that **do not** cause the participant significant distress but which may incidentally lead to discovery of ill health or concerns about wellbeing in a participant.

c) Proposals which investigate existing working or professional practices among participants at the University of Surrey researcher's own place of work, where these participants are identifiable to the researcher.

d) Research proposals to be carried out by persons unconnected with the University, but wishing to use staff and/or students as participants.

In addition, proportionate review may take place for studies where a University of Surrey researcher is Co-investigator (CI) on a project led by a Principal Investigator (PI) at another institution which would qualify for full review under 2.1.2 and where the University of Surrey researcher is responsible for the design of a questionnaire or other intervention and/or has participant contact, provided that project has completed the ethical approval process at the institution of the PI.

Note: Proportionate reviews usually benefit from a shorter turnaround time Submissions for proportionate review may be referred for full review if the initial reviewer identifies significant ethical issues.

Questionnaires/surveys that use students as participants do not necessarily require review by the UEC or Faculty Ethics Committees unless they meet one of the criteria above. However, it must be recognised that the University has a duty of care to its students. All surveys wishing to use students as a data source must go to the Students' Union, who then post the survey on their intranet, students then self-select to participate in any given survey. No general email call to students is allowed. For help with looking for student research participants please contact the Students' Union or your Faculty.

2.1.4 Self-assessment (only if none of the study procedures qualify for NHS review or full or proportionate UEC review)

All other research involving human participants may be self-assessed by the researcher. This includes (but is not restricted to) the following:

a) Anonymous national / regional student / staff / marketing surveys of which the contents are not designed by the University of Surrey (this does NOT automatically include validated questionnaires, survey instruments and other assessment tools).

b) Proposals which involve compensation to participants in the form of reimbursement for out of pocket expenses, refreshments, or a low-value prize draw, or where the compensation amounts to no more than the minimum hourly wage or a maximum of £100 in total.

A self-assessment form should be submitted online, following the instructions on the Research Ethics webpages for all research involving human participants where NHS review, or UEC full or proportionate review are not required. These self-assessments, as well as studies that have received NHS REC or UEC review, may be subject to monitoring and audit.

Self-assessment does not in itself constitute support for a favourable ethical opinion: a favourable ethical opinion may only be issued on the basis of a full or proportionate ethical review by the relevant ethics committee, as appropriate. All research is required to abide by the provisions of the Ethical Principles and Procedures on Teaching and Research and the Code on Good Research Practice as well as any other relevant University policies and external regulations. If required by funding bodies, publishers, or other monitoring authorities researchers may contact the RIGO to request issue of a letter confirming that the researcher has completed the self-assessment.

Where significant changes are made to the protocol the self-assessment should be repeated and the project submitted for review as appropriate. For governance purposes, all study protocols and associated documentation such as information sheets and consent forms should have version numbers and dates, whether they are submitted for review or not.

2.2 Where to submit your protocol

The UEC is responsible for reviewing protocols submitted by **Postgraduate (Research)** students, **staff** and **all other groups**.

Faculty Ethics Committees (FECs) are responsible for reviewing protocols submitted by **Undergraduate** and **Postgraduate (Taught)** students in their Faculty, including those on practitioner Doctorates (e.g. PsychD, DClinPrac, DBA).

2.3 Research supervision

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.

2.4 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.

2.5 Research conducted outside of the UK

The researcher should, where possible, refer to country-specific guidelines for the location where research is being carried out. The International Compilation of Human Research Standards is a listing by the US Department of Health and Human Services of over 1,000 laws, regulations, and guidelines (including ethics committees) on human subjects' protection in over 100 countries and from several international organisations. Details of country-specific requirements and how these are met should be included in protocol submissions (even if this is to confirm that additional action is not necessary).It is also recommended that researchers confirm they are covered by the University's travel insurance and they should ensure that their visa will allow for research to be conducted . Researchers going abroad should also regularly check the British Foreign Commonwealth Office website for further details and travel advice for the country they are planning to travel to.

3. RESEARCH INVOLVING HUMAN PARTICIPANTS

3.1 Teaching experiments

Teaching experiments and research studies involving blood sampling or the handling of blood and other human specimens must be carried out in accordance with the Human Tissue Act, 2004 and the University's Code on Good Research Practice.

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 University's Ethical Principles and Procedures for Teaching and Research;

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

c) that the student/participant 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 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 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.

If the results of the above mentioned activities are to be used for research purposes then the project should be evaluated against the criteria for ethical review (section 2.1). In addition, if students' data (demographics, personal data, work contributing to their degree) are to be used in a different way than described in the University's IP policy or the research otherwise goes beyond the terms of consent implied by the student's participation in the teaching activity, then additional consent to take part in the research should be sought.

3.2 The use of animal tissues in teaching

Procedures are not carried out on living animals for educational purposes. Some fundamental principles in biology and physiology may be taught using body tissues. If this is the case the In vitro experiments are carried out using tissues isolated from animals (which would be derived from animals used for research purposes) following euthanasia using humane methods approved under the Animals (Scientific Procedures) Act 1986 (amended regulations 2012). Wherever possible, animal use is limited by replacement with appropriate educational alternatives.

Any student may decide that they do not wish to participate in any particular experiment making use of tissues isolated from animals, 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.

Useful links:

Guidance on the Operation of ASPA

Understanding Animal Research

National Centre for the Replacement, Refinement and Reduction of Animals in Research

3.3 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.

If the results of the below tests are to be used for research purposes then the project should be evaluated against the criteria for ethical review (section 2.1). If outcomes are not used for research purposes, then the procedure below should be followed.

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) declining or accepting to participate shall not 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 student about the variations between individuals for that measurement;

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 student 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 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.

3.4 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 meets any of the criteria in section 2.1 the questionnaire along with other relevant documentation should be submitted to the relevant Ethics Committee. Other questionnaires need not, of necessity, be submitted for ethical review, 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 participants 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 participant is a student, the questioner or tester shall inform the participant if completion of the questionnaire or attendance at a test is an obligatory part of the participant's programme, or will in any way contribute towards the participant's final assessment.

c) Notwithstanding the agreement of an individual to participate in any questionnaire, survey or testing covered by the guidelines above, he or she may, at any stage, withdraw that agreement.

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

e) 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.

f) 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.

g) 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.

h) 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.

i) Provided that the conditions specified at the end of section 2.1 are met 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.

j) 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.

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

Note: Clinical Trials are statutorily defined as: "any clinical research requiring clinical trials authorisation from the Medicines and Healthcare Products Regulatory Agency under the Medicines for Human Use (Clinical Trials) Regulations 2004"

a) A signed statement from all participants shall be required certifying their 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. The consent form should make it clear whether data collected up to withdrawal can be withdrawn.

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

g) 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.

h) Once a favourable ethical opinion has been obtained for a project 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 and will indicate that a favourable ethical opinion has been obtained.

i) 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.

j) Every instance of a proposal involving the administration of drugs to participants shall be presented to the relevant appropriate regulatory, ethics and governance bodies notwithstanding the fact that it might appear to comply with these Guidelines.

k) 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 shall be notified to the relevant Ethics Committee(s) at the time of submission.

l) 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 relevant Ethics Committee(s).

m) 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.

n) In the case of experimentation it is always the responsibility of the researcher concerned to contact Business Support Services (extension 9008) to confirm or arrange insurance cover for the University.

o) The appropriate regulatory, ethics and governance bodies must be informed and consulted if any significant material change is made to a protocol that has already had a favourable ethical review.

p) 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 reported to the appropriate regulatory, ethics and governance bodies.

3.6 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 relevant 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.

4. GENERAL CONSIDERATIONS

4.1 Personal payments to investigators, Faculties/Departments and institutions

Personal payments received by investigators, and their pecuniary relationship with any sponsoring company has ethical implications.

Details of specific payments to investigators, Faculties/Departments or institutions must 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 must advise the Committee of this situation, but further details of such payments will not normally need to be declared.

4.2 Insurance

(See Appendix II for an Ethics, Insurance and Contracts Overview)

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.

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 £10m per claim and £12.5m 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 or membership of another relevant professional body.

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

j) Ethics Insurance Contracts Overview

It is critical to identify sponsor responsibilities and liabilities for any Clinical Trials and Clinical Research Studies which the University of Surrey conducts to ensure that the proper agreements are in place.

It is an insurance requirement that we ask what arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management/design/conduct of the research. Non-compliance with insurance terms and conditions could leave the University exposed to large law suits for which it has no cover.

All Clinical Trials/Clinical Research Studies must go through the relevant ethical review process as described in section 2.1; if the study does not have a favourable ethical opinion from the appropriate Ethics Committee, indemnity is not assured. Research Ethics Guidance has been produced for staff/students which summarises the ethical review. The current criteria for submission to the UEC can be found in section 2.1 and on the Research Ethics webpages.

The Legal Contracts Team, who negotiate all contracts for the University, establish at the outset of all studies, including all clinical trials and clinical research studies, that all Third Parties: i.e. Sponsors/Collaborators/Contract Research Organisations

hold appropriate legal liability insurance as the University's insurance policies do not provide an indemnity for their acts and omissions.

The University's Public Liability and Clinical Trials insurance policy provides an indemnity to University of Surrey for potential liability for harm to participants during the conduct of the research. Where studies involve NHS patients, the existence of University insurance does not in any way affect an NHS Trust's responsibility for any clinical negligence on the part of its staff, including a Trust's responsibility for University employees acting in connection with their NHS honorary appointments. The NHS hold an overriding responsibility and duty of care to all NHS patients participating in research studies, even if they are conducted on University premises where the studies are conducted by NHS employees or those researchers holding NHS honorary contracts.

The Ethics/Insurance/Contracts flow chart produced by the Legal Contracts Team which sets out this process, along with the key contacts which can be found in Annex IV.

4.3 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.

4.4 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.

4.5 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 Ethical Principles and Procedures for Teaching

and Research) undertaken by researchers, where relevant, from outside the University, whether those projects are externally or University-based, shall be submitted to the Student's GP. This information will be subject to the usual requirements for the preservation 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 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 Research Integrity and Governance Office and shall include details of the amount of financial inducement concerned, the nature of the contract and the medicine or appliance to be evaluated.

4.7 Payments to participants and/or organisations

Payments can be made to individual participants to reasonably reimburse them for time and for direct expenses.

Payments can be made to organisations to offset direct costs of providing for research to take place e.g. postal costs, room hire. However, it is unusual for any other fee to be paid and any payments of this nature should be clarified with your Faculty (if appropriate) and the Ethics Committee.

4.8 Data Protection Act, 1998

The Data Protection Act 1998 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.

iv) that personal data should not be stored on home PCs

v) that, where data is stored on laptops, the laptop is secure e.g. password protected

Consent forms should contain a paragraph (see Research Ethics webpages) regarding data protection; however the researcher is able to amend this as appropriate.

If the Researcher requires consent for the personal data to be transferred outside the EU then explicit consent for this should be obtained.

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.

4.9 Data Retention

Research Data - the University considers Research Data to be any material collected, observed or created for the purpose of analysis and on which research conclusions are based. Research Data must be retained for a minimum of **ten** years from completion of the project.

Research Project Data – this is data collected as part of the administration of the research project but is not analysed to draw any research conclusions. Such data are contact lists, consent forms, signed contracts and variations, funding bid documents, timesheets, copies of invoices, progress monitoring records, questionnaires, information packs for participants, monitoring returns, steering group minutes, feedback forms relating to research projects. Research Project Data must be retained for a minimum of **six** years from completion of the project.

Further information can be sought from the University Records Management and Information Compliance Officer or via the Research Data Management pages.

4.10 Auditing of Protocols

A sample of all protocols received by the Ethics Committees as well as those submitted as part of self-assessment are audited at a later date. The University uses the audit process to identify any gaps in processes or sharing of information across the University. Where any concerns are raised by the auditing staff, these are discussed informally with the researcher to provide advice on how to proceed. Researchers are contacted by the RIGO in the event of their protocol being selected for audit.

4.11 Amendments and the expiry of a favourable ethical opinion

The UEC 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. A further submission to the Ethics Committee will be required in the event that the study is not completed within five years. The Committee should also be advised when your research project has been completed or has been terminated early.

4.12 University Ethics Committee: Appeals Procedure

Following a decision of the University Ethics Committee not to grant a favourable ethical opinion, the Principal Investigator will have the right to appeal this decision according to the rules described below. The appeals procedure should **only** be

implemented when the University Ethics Committee and the Principal Investigator fail to reach agreement following comprehensive dialogue.

If the University Ethics Committee finds it is unable to grant a favourable ethical opinion, it will inform the Principal Investigator, in writing, of its decision and shall state clearly the reason(s) behind its decision.

The Principal Investigator has 14 days from the date of the written notification from the University Ethics Committee to petition the Vice Chancellor for an appeal. The Principal Investigator must state clearly the grounds upon which the request is based. Appeals should be based on one or both of the following:

- a failure on the part of the University Ethics Committee to follow its own procedures;
- a perverse decision by the University Ethics Committee*.

(* a perverse decision is one which no other University Ethics Committee, which has been provided with the same level of information from the applicant, would reach)

A direct challenge to the academic judgement of the University Ethics Committee will be considered insufficient for the granting of an appeal.

On receipt of a request for an appeal against a decision of the University Ethics Committee, the Vice Chancellor will determine whether or not to grant an appeal hearing. In so doing, the Vice Chancellor may seek advice and may, as necessary, interview either, or both of, the Chairman of the University Ethics Committee and the Principal Investigator. If the Vice Chancellor determines not to grant an appeal hearing, the decision of the University Ethics Committee will stand.

Should the Vice Chancellor permit an appeal hearing, he will direct the Academic Registrar to establish an appeal panel with the following membership:

- a Chairperson who will be a Deputy Vice Chancellor;
- two senior members of academic staff from Faculties other than that of the Principal Investigator.

In hearing the appeal, the panel will interview separately the Chairperson of the University Ethics Committee and the Principal Investigator. The Principal Investigator may be accompanied at the hearing, where appropriate, by another person connected to the proposed research project. The panel may also interview other persons as it deems necessary. The panel will inform the Academic Registrar of its decision and the reasons behind it; this will then be communicated in writing to both the Chairperson of the University Ethics Committee and the Principal Investigator within 7 days. The decision of the appeal panel will be final.

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(s) – to be appointed for a period of up to three years through agreement of the Committee members

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:

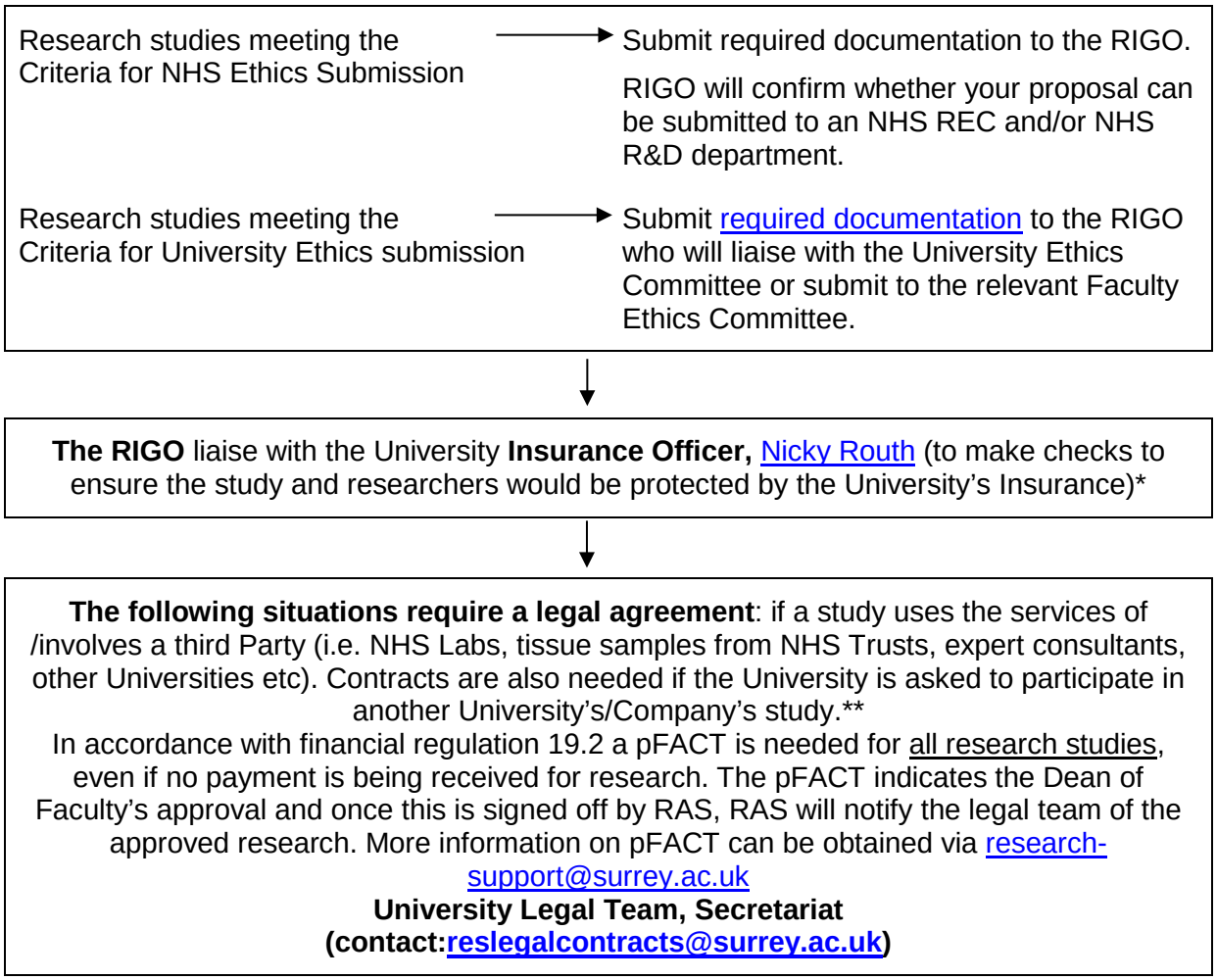
- *Faculty of Arts & Social Sciences*;
- *Faculty of Engineering & Physical Sciences*;
- *Faculty of Health & Medical Sciences*;

Student Representation – Up to three members

In Attendance – Secretary

APPENDIX II

Ethics, Insurance and Contracts Process Overview



*** Third Party Insurance -** During any contract negotiation the Legal Team will request sight of a third Party's insurance cover.

For Clinical Trials, this must be sent to the University's Insurance Officer for approval.

Studies involving NHS Patients - The NHS hold a duty of care towards their patients and for all NHS studies involving NHS patients (even when conducted at the University) the NHS shall be liable for any negligent harm caused to patients by NHS employees or researchers holding NHS honorary contracts. Important therefore for University researchers to hold NHS honorary contracts when involved in these studies.

Commercially Sponsored Clinical Trials - the Sponsor must provide a 'no-fault' indemnity which means they will be liable for harm caused to a participant of a study which resulted from the application of study drug and/or Protocol. **This protects the University and is a requirement of our insurers.**

****Contracts** – a contract with a third party will **identify the liabilities** each party takes on during that research study and will request any necessary **indemnities** required from the third party. **Legal team** will consider which type of contract is suitable such as: Clinical Trial Agreement; Collaboration Agreement; Subcontract; Consultancy Agreement; Material Transfer Agreement.