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**ETHICS: GUIDANCE AND PROCEDURES FOR
UNDERTAKING RESEARCH INVOLVING HUMAN
SUBJECTS**

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GUIDANCE

SECTION 1: INTRODUCTION

- 1.1 This handbook provides general guidance for academic staff, undergraduate and postgraduate students about the ethical issues which can arise in the conduct, supervision and utilisation of research involving human subjects and emphasises the need to work within professional codes of conduct and legal statutes. Further information accompanies the application form.

SECTION 2: GUIDING PRINCIPLES

- 2.1 Research involving human subjects is a moral enterprise invested by mutual respect and trust between participants and investigators. Maintenance of integrity in the professional conduct of research encompasses responsibilities to participants, funding agencies, employers, colleagues and students. Professional bodies emphasize the need for democratic values, respect for persons, knowledge and the quality of research to inform its conduct, whilst acknowledging conscientiousness, honesty, courage, and diplomacy to be desirable attributes of researchers.
- 2.2 In the conduct of research any potential, foreseeable risks to the physical, psychological, social well being, health, values and dignity of participants should be removed. It is the potential vulnerability of participants and their need for respect and protection that justifies ethical reviews of research and against which its acceptability is judged. “Every research project involving human subjects should be preceded by a careful assessment of the predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society” (Declaration of Helsinki).
- 2.3 Respect for autonomy, beneficence, non-maleficence, and justice are fundamental and widely accepted ethical principles relevant to research. Respect for these principles lies at the heart of recent human rights legislation (Human Rights Act 1998). Three articles within this act are particularly relevant to safeguarding the rights of research participants, minimising risks, and ensuring informed consent, privacy, anonymity and confidentiality.
 - Article 3: No-one shall be subjected to torture or inhuman or degrading treatment
 - Article 8: Everyone has the right to respect for his/her private and family life, his/her home and correspondence
 - Article 9: Everyone has a right to freedom of thought, conscience and religion.
- 2.4 Respect for autonomy – ‘self-rule’ – requires that individuals have the right whether or not to participate in a research study, free from coercion and without prejudice. Researchers in positions of authority should bear in mind that a coercive element might be inadvertently introduced in recruitment of participants i.e. students recruited into a study by academic staff, or by use of financial inducements. Respect for autonomy also imposes obligations on researchers to respect the anonymity, privacy and confidentiality of information relating to participants.
- 2.5 The principle of beneficence requires that researchers act to do good i.e. promote the well being of participants; non-maleficence emphasizes the need “above all to do no harm”. Researchers owe a duty of care to participants and liability can arise where this duty is breached and harm is incurred.

- 2.6 Considerations of beneficence and non-maleficence make it necessary for researchers and ethics committees to evaluate potential benefits versus risks to participants. Benefits to participants can include access to an intervention which is beneficial and which in normal life might be restricted; increase in knowledge and esteem resulting from interaction with a non judgmental and impartial researcher; financial gain and altruistic satisfaction that results of the research may benefit society.
- 2.7 Set against these benefits are potential risks which may be trivial or sufficient to result in discomfort or distress. Normally, risks to participants should not exceed minimal risk *ie.* not greater than that ordinarily encountered in daily life. Within the context of risk, attention is drawn to the following.
- The need for researchers to recognise and work within their boundaries of expertise and competence.
 - The need to inform participants of any emerging information during an investigation that could present psychological or physical problems or pose a risk to the well being of the participant.
 - The need to identify factors in a research protocol or procedure which could exacerbate risk *eg.* a pre-existing medical condition. Participants should be advised of these and any preventative actions.
 - The need to be aware of situations either foreseeable or unexpected which can arise in research and require an intervention on ethical grounds to safeguard the welfare of participants. This may require abandoning data collection.
- 2.8 The principle of justice as fairness encompasses the rights of research subjects to fair treatment and privacy. This includes the following:
- Non-discriminatory selection of subjects based on inclusion criteria which allows an equitable sharing of risks and benefits.
 - Respecting rights of individuals to decline to take part in a study or withdraw at any time without penalty, irrespective of any financial agreement.
 - Safeguarding participants' rights in accordance with the Human Rights Act (1998) regarding privacy, anonymity, confidentiality.
 - Facilitating participants' access to researchers to clarify points of information and providing immediate help should any harmful physical or psychological effects be experienced.
 - Honouring financial agreements agreed at the time that informed consent was obtained from participants.
 - Adherence by researchers to research protocols agreed by University and Faculty Committees concerned with research ethics. Amendments to protocols should be approved.
 - Debriefing participants at the conclusion of a study or following the completion of data collection to provide information, clarify any issues or misconceptions, monitor any negative effects which were unforeseen and require intervention.

SECTION 3: PROTECTING RIGHTS, ENSURING SAFETY OF RESEARCH PARTICIPANTS

- 3.1 Identifiable safeguards should be in place at the onset of a research study which are designed to protect against physical, psychological and social harm. If there is a foreseeable possibility of discomfort or distress, individuals should be warned of this at the time that informed consent is obtained.
- 3.2 Potential risks or costs to research participants can arise from intensive, invasive techniques of biological, psychological or social origin, loss of privacy, time or financial resources. Faculty Committees concerned with research ethics, through their procedures and protocols

ensure appropriate screening is in place, designed to minimise risks and costs. Various standards for use of specific techniques and tests have been developed by professional expert groups and professional bodies.

- 3.3 Researchers should incorporate sensitivity in their approach, and be aware of the need for mindfulness and respect regarding religion, cultural and gendered differences in research populations.
- 3.4 Voluntary, informed consent should be sought from participants in a research study *ie.* freely obtained without pressure or coercion or undue influence. Appropriate time should be allowed for participants to reflect on and consider information before they agree to take part.
- 3.5 In seeking voluntary consent, researchers should emphasise that potential participants have a right to refuse to take part and to withdraw at any time without detriment. Participants may withdraw at the concluding, debriefing stage of a study and require destruction of their personal data.
- 3.6 Consent should be obtained in writing, although verbal consent is acceptable in certain circumstances. Written consent is recommended for studies involving minimal risk or discomfort. In obtaining consent the following are important components:
 - Participants should be provided with information about the purposes of an investigation, duration, sources of funding and the nature of commitment required from them.
 - Potential foreseeable risks/discomforts should be explained.
 - Information should be provided in clearly understood language or consent is invalid. Avoid jargon and use of complex technical terms.
 - The nature of confidentiality and anonymity should be made clear to participants.
 - Points of access for further information should be identified, and the arrangements, if appropriate, for debriefing.
 - In some forms of field research it may be necessary for consent to be re-negotiated over time and not regarded as a one-off event.
 - A person who is fully informed and who volunteers to complete a research questionnaire implicitly consents to participation in that research.
- 3.7 It is recognised that, although as a general rule studies involving human participants should be carried out with consent, there are some exceptional circumstances and methodological approaches where consent is not obtained for justifiable reasons. Guidelines are available from professional bodies concerning such research approaches, and should be followed. Faculty committees concerned with research ethics can provide further guidance on this matter. Covert research and deception is also addressed within the guidelines of specific professional bodies.
- 3.8 Children or vulnerable adults are those who do not have full autonomy of thought, will or action. This can be variable in degree and may render the individuals vulnerable to side effects or other risks due to their physical, emotional, cultural or social status. Problems which can arise include failure to comprehend or weigh up information, or to be physically incapable of signing a consent form. Children (minors), pregnant women, older adults and those with mental illness, learning disability, chronic illnesses and neurological impairment are exemplars of vulnerability.
- 3.9 Special arrangements relate to obtaining informed consent in vulnerable groups, as in the examples given below. Witnessed consent may be necessary in the presence of impairment.

Children (Minors)

- Assent of a child over 7 years of age should usually be sought directly from the child. In addition, consent should be sought from a parent /guardian if the child is under 16.

Guidelines involving research in children have been developed by a number of professional bodies. BERA¹ (2004) states that:

‘Care should be taken when interviewing children and students up to school-leaving age; permission should be obtained from the school and if they so suggest, the parents’. The RCP² (1996) and BPA³ (1992) both make the point that consent should be obtained directly from children, with supplementary assent/consent from parents/guardians.

- Further to this, the BPA point out that if children give consent to participate and subsequently avoid the research procedure/test, this should be taken as evidence of failure to consent and effective withdrawal from the study.

Pregnancy

- CIOMS/WHO⁴ [1993] guidelines advise that no special problems of eliciting consent exist in the case of pregnant and nursing mothers. However, many Committees require that consent is not sought in the time period around childbirth.

Learning Disability

- Many individuals are competent to understand the implications of research participation; difficulties arise where competence/rationality is impaired. In the latter case, the RCP (1996) guidelines covering non-therapeutic and therapeutic research offer clear direction to researchers. It should be emphasised that UREC/FREC do not consider proposals relating to hospitalised individuals which should be submitted to an NHS LREC.

Mental Health

- A key issue is the need to gauge whether or not a potential participant is too vulnerable to take part in the first place. Occasionally researchers will be asked by a participant directly for advice or information which conflicts with their role as researcher or interviewer. It will be helpful to have a list of local resources and helplines, including advocacy services to help in this situation to avoid being drawn into helping someone with an individual problem. The context and subject of the research will have some bearing on the need for support. If research is being undertaken with people in hospital or in a vulnerable situation, the need to have some forms of support available will be greater.

3.10 Confidentiality

All research should conform with legislation related to data protection. Researchers should make clear to participants the nature of any promises on confidentiality or restrictions on the use of data. Unless agreed to the contrary in advance, information about participants is confidential. Anonymity is subject to the same conditions.

SECTION 4: FUNDING AGENCIES

4.1 In negotiations with funding agencies and other key stakeholders it is advisable that researchers consider the following prior to signing contracts:

- Funding agencies/sponsors should be disclosed by researchers (maximum openness desirable).
- The starting point is that the University as the employer of a researcher will own all data, results and intellectual property rights created by a researcher in research studies conducted in their employment. However, exceptions apply according to the contractual

¹ British Educational Research Association

² Royal College of Physicians

³ British Paediatric Association

⁴ Council for International Organisation of Medical Sciences/World Health Organisation.

arrangements with the sponsor. For example if a sponsor is paying 100% of the full economic cost of a project, they will usually expect the resulting IPR to be assigned to them. Even so, most sponsors will be happy to licence that IPR to the University for research and academic purposes and this should usually be requested.

- The starting point for students (who are not also employed by the University), is that they own their own IPR. It is therefore usually advisable where non-employed students are involved in a project, to obtain their written assignment of their IPR to the University, before commencing work on the project.
- Researchers should consider whether they are bringing any existing IPR to the project, and whether they are happy for the sponsor to be able to continue using this IPR after the project has finished.
- Funding agencies/sponsors and other organisations should respect the rights of researchers to maintain confidentiality of data.
- Funding agencies/sponsors and other organisations should respect the freedom of researchers to publish findings without censorship. (Defined as exerting undue influence/interference in the conduct, analysis, findings and dissemination of research). Contractual clauses relating to the sponsor's right to prohibit publication in order to protect their IPR, must be considered carefully.
- Appointment of advisory groups can be helpful in project management of contract research. Such groups represent legitimate interests of key stakeholders and should operate within clearly defined terms of reference.

4.2 Obligations of funders and researchers should be clearly stated in a written contract of negotiated terms and conditions. Researchers have a responsibility to be fully conversant with the content of such contracts, and conditions should not be accepted which conflict with a researcher's professional codes of conduct. The following points should be borne in mind in any contract negotiations:

- During contract negotiation researchers should clarify rights to publish and disseminate results of their work.
- During contract negotiation researchers should clarify the rights to intellectual property rights, whether arising from the research, or in existence before the research. Who will own the resulting IPR? Who has the rights to use the existing and resulting IPR once the research has been concluded?
- Researchers cannot engage in contract research without the agreement of the University⁶
- Researchers should make clear to funders the benefits and limitations which may result from proposed investigations, but they should make it clear that they are not guaranteeing any particular outcome or result.
- Researchers should not undertake research outside of their expertise
- Research should not be undertaken where resources (time, personnel, finance, equipment) are inadequate to achieve the project aims.

Funding agencies are entitled to receive financial audits/records of expenditure on research grants, reports, (interim and/or concluding) detailing methods, findings, implications, and recommendations of an investigation. Funders may exercise the right to see a final report before publication.

Researchers have responsibilities to notify/seek approval from funders (and faculty committees concerned with ethics) of any departure from an agreed plan or conditions of investigation. Referral for independent arbitration or mediation may be necessary where resolution of a dispute cannot be achieved. It is vital that researchers should identify any

⁶ Normally the Faculty Dean.

conflicts of interest which may arise in the conduct of a project and require pre-emptive resolution.

PROCEDURES

SECTION 5: WHICH STUDIES REQUIRE ETHICAL APPROVAL?

5.1 It is the responsibility of all researchers to ensure that a study is conducted in accordance with the ethical principles appropriate to their discipline/professional body and more general guidance summarised in this handbook. Any unanticipated problems which arise during a study must be reported to the project supervisor, lead applicant, or the Chair of the Faculty Research Ethics Committee. It is the responsibility of academics to ensure that the ethics guidance is complied with for undergraduate/ postgraduate projects.

5.2 Studies involving human subjects which can raise ethical and/or legal issues and are likely to require scrutiny are summarised below:

- investigations involving invasive biological techniques
- investigations that intrude psychologically, socially or culturally
- investigations involving vulnerable groups/individuals;
- those leading to loss of participants' privacy, time and financial resources.

5.3 Studies which involve links with certain external organisations/countries in relation to funding of proposals, sponsorship of research students, or collaboration/research partnerships can give rise to ethical concerns, whether or not they require the participation of human subjects. These encompass:

- external organisations which sell products injurious to health or life;
- external organisations which damage or pollute the environment;
- countries with oppressive political regimes/human rights records;
- organisations involved in animal experimentation.

Researchers should seek advice from the Chair of their Faculty Research Ethics Committee (FREC) or of the University Research Ethics Committee (UREC).

5.4 There are a number of straightforward research proposals involving human subjects where it may not be necessary for researchers to seek ethical committee approval. Proposals which may come into this category include the following:

- questionnaires and interview schedules where there are no major issues relating to confidentiality, or sensitive information;
- research already given approval by other ethics committees which have established reciprocal arrangements with the University through UREC;
- procedures authorized by faculty committees as being appropriate for self-regulation.

However, in these cases the researcher still has a responsibility to consider ethical issues and take note of any relevant codes of conduct/practice, and this may be supplemented by Faculty requirements.

5.5 The pre-application checklist should assist potential applicants in deciding whether there is a need to seek ethical approval. If any doubt exists about ethical issues related to a project, it

should be referred to the FREC in the first instance and then to the University Research Ethics Committee, if necessary.

SECTION 6 ETHICAL CLEARANCE: PROCEDURES

6.1 All applicants wishing to obtain ethical clearance should obtain information regarding annual dates of meetings/timescales for scrutiny of proposals from the Chair of their Faculty Research Ethics Committee (FREC). Completed forms should be returned to the FREC. If after reading these guidelines together with those of the relevant professional body, any uncertainty exists about the need for ethical approval, prior to submitting the necessary documentation the advice of the Chair should be sought.

6.2 For **postgraduate students** completing MA/MSc by research or MPhil/PhD, Fig 1 summarises the process of ethical clearance. Faculty Research Degrees Committees are obliged to seek approval from faculty committees concerned with research ethics before making any decisions related to the following:

- students applying for MA/MSc by research, MPhil or PhD whose outline project plan gives rise to ethical considerations;
- students whose present, past or proposed future work gives rise to ethical considerations which are apparent either at the point of seeking transfer from MPhil to PhD (under 1996 Regulations), or as part of the annual monitoring process.

The registration form for a research degree (RD3) plus form RE4 should be completed for ethical clearance where research involves human subjects and should be signed by the applicant and the supervisor.

6.3 **For diploma/undergraduate students, postgraduate taught courses (MA/MSc), staff research and applications from external researchers** who wish to base part or all of their project within Kingston University, the RE4 form should be completed and signed by the lead and co-applicant(s). Where the lead applicant is a student the supervisor should also sign the form and is responsible for ensuring that all procedural stages are completed. Normally, it is not necessary to have received ethical clearance prior to submitting a research proposal to a funding body, however, exceptions do exist. It is the responsibility of researchers to ensure that the timing of ethical clearance for their proposals meets the requirements of funders.

6.4 Undergraduate research projects involving human subjects may be covered under the delegated approval scheme.

6.5 Delegated approval transfers the right and responsibilities to project supervisors, or other nominated academic member of staff, to approve and monitor undergraduate research projects within the approved parameters, using standard routine methodology. Delegated ethical approval should be granted by a Faculty Research Ethics Committee to module leaders/project supervisors.

6.6 **Non funded research conducted by staff involving human subjects**

Attention is drawn to Appendix 1 Legal Responsibilities and paragraph 1.4 concerning indemnity.

6.7 Procedures for ethical approval of research proposals by faculties and the University Research Ethics Committee encompass the following:

- Researchers (or other advocates of a proposal) are not normally required to attend meetings of an ethics committee.

- The advice of appropriate specialists may be sought in circumstances where the committee deems this necessary, but these individuals will not be involved in making a decision.
- If members of an ethics committee have a direct involvement in a research proposal, such interests should be declared and the discussion conducted in their absence.
- Committees may approve or reject a proposal, or require amendments. It may be necessary to defer a decision to obtain clarification or further advice about a proposal.
- Applicants may appeal to the ethics committee against a decision to reject or require amendments. An appeal should be made to the committee chair within 21 working days. No further rights of appeal are allowed after the committee has considered an appeal.
- Applicants should be notified of the decision of an ethics committee within 7 working days.
- Where a decision regarding ethical clearance of a proposal is required before the next available meeting of the committee, the chair may use discretion to make a decision after consultation with other members by circulation of papers. Any actions taken by the chair shall be reported to the next committee meeting.

6.8 **Monitoring**

- Following ethical approval of a proposal no changes should be made to the protocol or membership of the research team without the consent of the research ethics committee.
- If unanticipated problems which generate ethical concerns arise during the course of a study these should be notified by the researcher or supervisor (as appropriate) to the or chair of the FREC to discuss whatever actions may be necessary to safeguard the welfare and interests of participants and/or researchers.

SECTION 7: EDUCATION AND TRAINING IN RESEARCH ETHICS: OPPORTUNITIES FOR STAFF AND STUDENTS

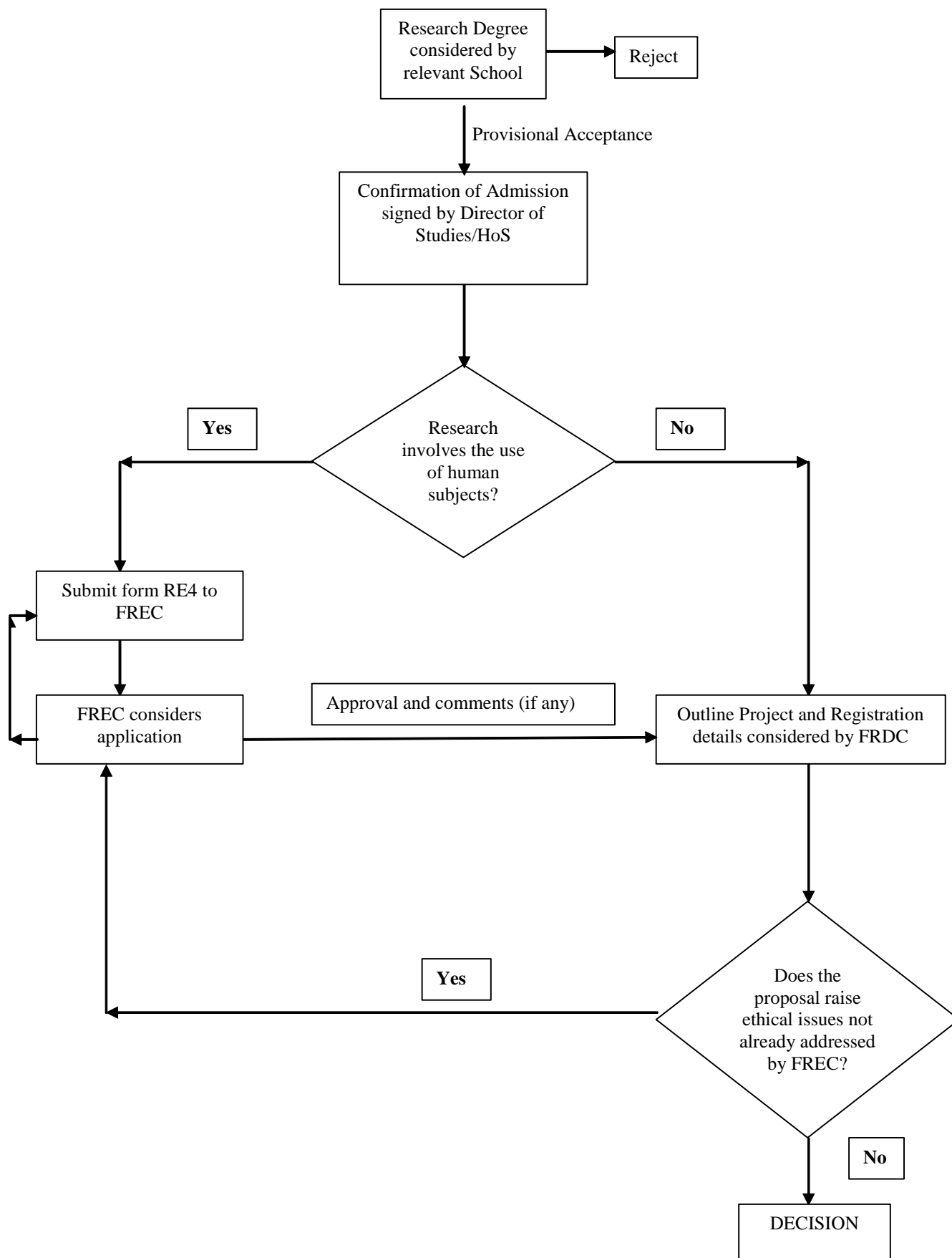
7.1 Education and Training: Research Ethics

- **Research Supervisors**
Provision of research supervisor training is addressed as part of the post-graduate certificate/diploma in teaching and learning in higher education. This is aimed primarily at new research supervisors and contains lectures on research ethics. The ethics lecture component can be accessed more widely by academic staff who wish to update their knowledge and skills. Further information can be obtained from the Academic Development Centre.

- **Undergraduate/Postgraduate Students**
Research ethics should form part of the content of research methods courses delivered at levels 6 and 7 within undergraduate and taught postgraduate programmes. The Graduate School also offers an ethics session for research students as part of its generic research student training.

- **External Courses**
A number of organisations hold short one/two day courses designed either to provide a training on general research ethics, or to address specialist, discipline - specific research ethics issues. Exemplars include:
 - * Department of Medical Ethics and Law, Kings College, University of London
 - * Professional bodies and Learned Societies listed in websites;
 - * Government websites including the National Research Ethics Service [NRES]
 - * Association of Research Ethics Committees (UK). This national organisation holds 3 annual meetings addressing a wide range of research ethics issues from an interdisciplinary perspective. Short training courses also available.
 - * Centre for Professional Ethics, University of Keele

Fig 1: The Process of Consideration of Research Ethics in Research Degree Programmes



ETHICAL REVIEW OF RESEARCH PROJECTS INVOLVING HUMAN PARTICIPANTS PRE-APPLICATION CHECKLIST

'Research is original investigation undertaken in order to gain knowledge and understanding. It includes: work of direct relevance to the needs of commerce and industry, as well as to the public and voluntary sectors; the creation, development and maintenance of the intellectual infrastructure of subjects and disciplines, in forms such as dictionaries, scholarly editions, catalogues and contributions to major research databases; the invention and generation of ideas, images, performances and artefacts including design, where these lead to new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and analysis of materials, components and processes, e.g. for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.'

Activities that meet this definition constitute research for the purposes of the Kingston University research ethics policy.

Any research that involves living human participants, and that is carried out on Kingston University premises and/or by Kingston university staff or by KU students under the supervision of KU staff requires ethical approval. Examples of human participation in a research study would include 1) obtaining data through intervention or interaction with the individual, 2) accessing identifiable personal information from any other source and 3) the collection or study of their organs and/or tissue (in accordance with the Human Tissue Act 2004 (Commencement No.1) Order 2005).

If you answer **YES** to any of the following questions, you **must** submit your project for ethical review prior to data collection.

If any doubt exists about ethical issues related to a project, e.g. if your research is being sponsored by an organisation or has collaborators with a vested financial interest in the outcome, it should be referred to the Faculty Research Ethics Committee.

Will your research involve living human participants?	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Will your research involve data on humans?	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>
Will your research involve human biological material?	YES	<input type="checkbox"/>	NO	<input type="checkbox"/>

If you are an **undergraduate student** working on your final project, your research may be covered under a module delegated ethical approval. Please check with your project supervisor whether or not you are covered. If **NOT**, you must submit an application for ethical approval prior to data collection.

Health and social care research: special note for projects involving the NHS (including Phase 1 studies involving healthy volunteers):

The National Research Ethics Service (NRES) for England works closely with the UK Health Departments to develop and maintain a common UK-wide system for ethical review of health and social care research.

Certain health and social care research projects require approval by an NHS Research Ethics Committee (REC) prior to commencement. For full details see <http://www.nres.npsa.nhs.uk/applications/>

NHS REC approval is required for any research proposal involving:

- 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 contracts with private sector institutions
- individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above
- access to data, organs or other bodily material of past and present NHS patients
- foetal material and IVF involving NHS patients
- the recently dead in NHS premises

- the use of, or potential access to, NHS premises or facilities
- NHS staff - recruited as research participants by virtue of their professional role
- Health-related studies taking place in a prison or a young offender institution in England and Wales
- Any study involving xenotransplantation (that is, putting living cells, tissue or organs from animals into people). Where such studies involve medicinal products which have been genetically modified, ethical review would be the responsibility of the Gene Therapy Advisory Committee (GTAC). Otherwise the application should be made to an NHS REC.

For details on all projects requiring NHS ethical review, see:
<http://www.nres.npsa.nhs.uk/applications/apply/ethical-review-requirements/#RequirementsGAfREC>

All applications to RECs in the Research Ethics Service are made using the Integrated Research Application System (IRAS). Except where research involves adults unable to consent for themselves in both England / Wales and Scotland, only one ethical review is required for any research study in the UK.

The Integrated Research Application System (IRAS) is a single online system for applying for permissions and approvals for health and social care/community research in the UK. IRAS can be accessed at www.myresearchproject.org.uk. IRAS contains extensive guidance to support researchers in completing their application form.

In completing your application, you should refer to the *Ethics guidance and procedures for undertaking research involving human participants*.

APPLICATION FORM FOR ETHICAL REVIEW RE4

SECTION A

Project title:

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Name of the lead applicant:

Name (Title / first name / surname):	
Position held:	
Department/School/Faculty:	
Telephone:	
Email address:	

Name of co-applicants:

Name (Title / first name / surname):	
Position held:	
Department/School/Faculty:	
Telephone:	
Email address:	

Name (Title / first name / surname):	
Position held:	
Department/School/Faculty:	
Telephone:	
Email address:	

Name (Title / first name / surname):	
Position held:	
Department/School/Faculty:	
Telephone:	
Email address:	

Is the project

- Student research
- KU Staff research
- Research on KU premises

Yes		No	
Yes		No	
Yes		No	

If it is STUDENT research: Course: _____

Supervisor/DoS: _____

SECTION B

Has approval for the project already been granted by another ethics committee?

Yes No

If **NO**, proceed to **Section C**;

If **YES**, please complete the rest of this section before going to the declaration in **Section D**:

Name of the committee: _____ Date of approval:

Please attach the submission made to that committee, together with the approval letter. The Faculty Research Ethics Committee (FREC) may require further information or clarification from you and you should not embark on the project until you receive notification from the FREC that recognition of the approval has been granted.

SECTION C

Briefly describe the procedures to be used in this research involving human participants

Summarise the data sources to be used in the project:

Estimate duration of the project (months): _____

State the source of funding: _____

Is it collaborative research?

Yes No

If YES, name of the collaborator institutions:

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

Provide a brief project description (max. 150 words). This should be written for a lay audience

Deception of participants, concealment or covert observation?	Yes		No	
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Will this research significantly affect the health* outcomes or health services of subjects or communities?	Yes		No	
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Note* health is defined as not just the physical well-being of the individual but also the social, emotional and cultural well-being of the whole community.

Is there a potential for enduring physical and/or psychological harm/distress to participants?	Yes		No	
--	-----	--	----	--

Does your research raise any issues of personal safety for you or other researchers involved in the project? (especially if taking place outside working hours or off University premises)	Yes		No	
--	-----	--	----	--

Will the research be conducted without written informed consent being obtained from the participants?	Yes		No	
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Will financial/in kind payments (other than reasonable expenses and compensation for time) be offered to participants? (Indicate in the proposal how much and on what basis this has been decided)	Yes		No	
--	-----	--	----	--

Is there a potential danger to participants in case of accidental unauthorised access to data?	Yes		No	
--	-----	--	----	--

N.B. If you have answered YES to any of these questions, you should address them fully in your project proposal and show that there are adequate controls in place.

Storage, access and disposal of data

Describe what research data will be stored, where, for what period of time, the measures that will be put in place to ensure security of the data, who will have access to the data, and the method and timing of disposal of the data.

SECTION D

To be signed by all applicants

Declaration to be signed by the applicant(s) and the supervisor (in the case of a student):

- I confirm that the research will be undertaken in accordance with the Kingston University *Guidance and procedures for undertaking research involving human participants*
- I will undertake to report formally to the relevant Faculty Research Ethics Committee for continuing review approval.
- I shall ensure that any changes in approved research protocols or membership of the research team are reported promptly for approval by the relevant Faculty Research Ethics Committee.
- I shall ensure that the research study complies with the law and University policy on Health and Safety.
- I confirm that the research study is compliant with the requirements of the Criminal Records Bureau where applicable.
- I am satisfied that the research study is compliant with the Data Protection Act 1998, and that necessary arrangements have been, or will be made with regard to the storage and processing of participants' personal information and generally, to ensure confidentiality of such data supplied and generated in the course of the research.
(Note: Where relevant, further advice should be sought from the Data Protection Officer, University Secretary's Office)
- I shall ensure that the research is undertaken in accordance with the University's Single Equality Scheme.
- I will ensure that all adverse or unforeseen problems arising from the research project are reported immediately to the Chair of the relevant Faculty Research Ethics Committee.
- I will undertake to provide notification when the study is complete and if it fails to start or is abandoned;
- (For supervisors, *if the applicant is a student*) I have met and advised the student on the ethical aspects of the study design, and am satisfied that it complies with the current professional (*where relevant*), departmental and University guidelines. I accept responsibility for the conduct of this research and the maintenance of any consent documents as required by this Committee.
- I understand that failure to provide accurate information can invalidate ethical approval.

Signature of lead applicant: **Date:**.....

Signature of co-applicant: **Date:**.....

Signature of co-applicant: **Date:**.....

Signature of co-applicant: **Date:**.....

Signature of supervisor:.....

Date.....

CHECKLIST

Please complete the checklist and attach it to your application:

Project title: _____

Lead Applicant: _____

Date of application: _____

Before submitting this application, please check that you have done the following: (N/A = not applicable)	Applicant			Committee use only		
	Yes	No	N/A	Yes	No	N/A
All questions have been answered						
All applicants have signed the application form						
The research proposal is attached						
Correspondence from other ethics committees is attached						
Informed Consent Form is attached						
Participant Information Sheets are attached						
All letters, advertisements, posters or other recruitment material to be used are attached						
All surveys, questionnaires, interview/focus group schedules, data sheets, etc, to be used in collecting data are attached						
Reference list attached, where applicable						

RESEARCH PROPOSAL GUIDELINES

Provide a description of the proposed research plan and procedures, using the following headings. Show clearly that the research protocol gives adequate consideration to participants' welfare, rights, beliefs, perceptions, customs and that cultural heritage, both individual and collective, will be respected in the course of your research.

Research plan and protocols

- What is the rationale for the research?
- What is the research design/method?
- Where will the project be conducted?
- What is the participant group(s) and why has it been selected?
- How many participants will be recruited and what is the rationale for that number?
- How, by whom, and where, will potential participants be selected and approached to receive the invitation to participate? (*Attach a copy of letters, advertisements, posters or other recruitment material to be used*)
- How much time will potential participants have to consider the invitation to participate?
- What is required of participants? (*Attach a copy of any testing protocols, interview schedules, data sheets, informed consent, etc to be used.*)
- *Relevant experience of researchers*
- Data storage and access to data
- *Explain how the information you receive will be analysed/interpreted and reported. What specific approaches or techniques (statistical or qualitative) will be employed?*
- Dissemination

Ethical consideration

- How will voluntary participation be ensured?
- Is active consent being sought from all participants for all aspects of the research involving them? If No, why not?
- How will participants' privacy be protected during the recruitment process, or access to tissue samples, or access to records?
- What are the benefits and risks to participants and how will risks be minimised?
- Are there any potential conflicts of interest for the researchers?
- Do the researchers have any affiliation with, or financial involvement in, any organisation or entity with direct or indirect interests in the subject matter or materials of this research? Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this research?
- Are there any restrictions on the publication of the results of this study? If yes, who has imposed them and what are they?
- Will the research involve payments/rewards/inducements to participants?
- How will confidentiality/anonymity of information received be ensured?
- Any other ethical issues specific to your research?

Risk/benefit analysis

- Clearly justify any potential risks to participants (however minimal) by the potential benefits of the research.
- Disclose any foreseeable risks (for example the discomfort of having your views challenged by others in a focus group, or that associated with negative feedback about a learning assessment).
- Direct benefit to participants
- How risks and benefits identified here will be communicated to the participants (e.g., through the informed consent document)?
- Identify any costs and compensation

APPLICATION FORM FOR CHANGE IN METHODOLOGY OR CHANGE IN MEMBERSHIP OF THE RESEARCH TEAM

Date of Original Ethical Approval: _____

Project Title:

--

Name of lead applicant (Title / first name / surname):	
Position held:	
Department/School/Faculty:	
Telephone:	
Email address:	

If it is STUDENT research: Course: _____

Supervisor/DoS: _____

On a separate page, describe and provide justification for the changes being proposed. Be concise and specific in describing changes in methodology that affect the experience of participants and/or relate to the risks/benefits of participation. Explain why these changes are necessary.

The proposed changes in protocol will necessitate changes in documents such as recruitment flyers, consent forms, debriefing forms, or other project-related documents.	Yes		No	
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If YES, attach a copy of the revised documents with changes highlighted.

CERTIFICATION OF LEAD APPLICANT

I certify that information contained in this request is complete and accurate.

Signature of Lead Applicant

Date of Signature

CERTIFICATION OF SUPERVISOR/DoS (If Lead Investigator is a Student)

I certify that information contained in this request is complete and accurate.

Signature of Project Supervisor/DoS

Date of Signature

CONSENT: PROFORMA/EXEMPLARS OF INFORMATION AND CONSENT FORMS

Informed Consent

- Please read section 3 of the Guidance which is relevant to obtaining informed consent from potential participants in a research study.
- An information sheet should be provided for participants to read prior to obtaining informed consent. This should describe in jargon free language what the research study is about and what taking part will entail. Depending on the method of recruiting participants the information sheet can either be handed directly to participants or could be written in the form of a letter. An example of the latter is provided overleaf. It is recognised that Faculties will provide other types of exemplars appropriate to different research approaches. Please consult your Faculty Ethics lead for further information.
- After potential participants have had time to consider their decision about taking part, written consent should be documented as shown on the form on page 24

INFORMATION AND CONSENT

Please append the letter inviting subjects to take part and explaining the study, as it will appear - *ie.* using your letterhead, etc. We recommend that the letters should follow the format below. If there is no written invitation and explanation, please justify.

Dear X

Study of _____ (simple and unafrightening title)

We are asking you if you would help us with a study which involves We are doing this study to find out If you agree, we would ask you to come on on and we would

Your name as a possible participant was accessed via

The side effects of _____ are but these are You need not take part in this study, and you can leave it at any time without affecting your education/relationship with the Faculty or University in any way.

All information we gain from you will be maintained in a strictly confidential manner. The only people who will have access to the information will be _____. After the project all raw data that can identify individuals will be destroyed. In the reporting of the project, no information will be released which will enable to reader to identify who the respondent was. We would / would not (delete as appropriate) reimburse your travel expenses. If you have any questions or problems, please contact me. My telephone number is _____

Yours sincerely

NOTES:

- Participants should be told if the study involves placebo treatments where applicable.
- Participants should be told how they would be allocated to different intervention groups where applicable.
- Participants should be advised of the rights: *eg.* To withdraw, to seek advice, access to results, etc.
- Try to use everyday words instead of jargon.
- Use "would" instead of "will" for the subjects actions, because their consent should not be assumed.

It is recommended that a form separate from the information sheet is developed for the respondent to document their consent.

WRITTEN CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Statement by participant

- I confirm that I have read and understood the information sheet/letter of invitation for this study. I have been informed of the purpose, risks, and benefits of taking part.

(Title of Study)-----

- I understand what my involvement will entail and any questions have been answered to my satisfaction.
- I understand that my participation is entirely voluntary, and that I can withdraw at any time without prejudice.
- I understand that all information obtained will be confidential.
- I agree that research data gathered for the study may be published provided that I cannot be identified as a subject.
- Contact information has been provided should I wish to seek further information from the investigator at any time for purposes of clarification.

Participant's Signature-----

Date -----

Statement by investigator

- I have explained this project and the implications of participation in it to this participant without bias and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator -----

Signature of investigator -----

Date -----

APPENDIX 1: LEGAL RESPONSIBILITIES FOR RESEARCH INVOLVING HUMAN SUBJECTS

- 1.1 There is no overriding legislative framework which specifically covers research work involving human subjects. There are, of course, statutes dealing with particular problems such as the Data Protection Act, the Mental Health Act, the Medicines Act etc. A Research Ethics Committee ('REC') would be expected to abide by the requirements of these items of legislation. However, in general terms, it is the common law of negligence which would apply to the activities of a Research Ethics Committee and researchers, as it does to all activities which involve risk. There are of course legal statutes such as the Data Protection Act, the Mental Health Act, the Medicines Act, Discriminatory (Equality) Law such as the Race Relations (Amendment) Act 2000, The Disability Equality Duty 2006 and any subsequent equality law that has specific mandatory duties. A Research Ethics Committee (REC) will be expected to abide by the requirements of statute law.
- 1.2 The general principle of negligence is deceptively simple: a person is liable for damage, injury or death caused by his or her acts or omissions the results of which should have been reasonably foreseeable. Therefore, it is essential that a person exercises the appropriate duty of care when carrying out his or her actions. However, the practical application of this legal principle is complex and is influenced by the often-ambiguous nature of the links in the chain of causation leading to particular events or results. The notion of 'reasonable foreseeability' can be remarkably elusive in legal argument. However, it is clear that a REC should be diligent in exercising a duty of care with regard to its proceedings and decision-making.
- 1.3 Liability arising out of negligence is always assessed in terms of the reasonableness of expectations as to the outcome of any act or omission and this would be measured against the procedures and preventative measures taken by the researcher, the REC (whose terms of reference and authority would be taken into consideration) and the institution – in this case the University. Since a REC is not a legal entity, liability would lie with its members jointly and severally. However, in practice, an injured party is more likely to sue the researcher whose work would be the immediate cause of injury or damage, or the institution which enables, allows or funds the research. The primary responsibility of researchers for negligent work can also be placed on students carrying out research under their supervision.
- 1.4 With regard to indemnity, members of the REC and researchers who are employees of Kingston University would be covered by insurance under Public Liability and Professional Negligence policies for any deleterious effects arising from their research work. This only applies where the research has been formally notified. Clearly, insurance can only protect both the University and its employees as far as material loss is concerned, it does not help with regard to the damage to the reputation of the University and the researcher which inevitably arises where negligence is attributed to a piece of research.
- 1.5 The following checklist should be taken only as a guide. It does not purport to replace sound legal advice. All researchers who are in doubt about their specific legal duties should make contact with the faculty committee concerned with research ethics in the first instance which may refer the matter to the University Research Ethics Committee and the University Secretary.
- 1.6 **Potential Criminal Liability for your Treatment of your Human Subject**
 - Where ***bodily contact*** is involved, for example, medical or health examinations are involved, the researcher must ensure that proper consent has been obtained. That consent must be informed consent, that is to say, it must be made clear to the human subject what that examination will entail. Transparency is vital. Where no consent has

been obtained, the researcher could be held liable for assault, battery and/or other offences against the person.

- Where **medicines or foods** are to be administered to the human subject, whatever the purpose of the administration, the researcher should observe that the Offences Against the Person 1861 provides that any person who unlawfully administers to or cause to be administered to or taken by any other person any poison or other destructive or noxious thing so as thereby to endanger the life of such person, or so as thereby to inflict upon such person any grievous bodily harm, commits an offence which is punishable with imprisonment. “Administer” refers to “conduct which not being the direct application of force to the [subject] nevertheless brings the noxious thing into contact with his body”. This includes the spraying of substances on a person’s face, underarms, fingernails etc. Informed consent from the subject should be obtained prior to the carrying out of any such tests but consent may not suffice where the experiment is unusual and infringes public policy, or likely to lead to serious harm.
- Experiments involving **nudity**⁵ either of the researcher or his/her human subject should observe the provisions of the common law misdemeanor of ‘committing an act outraging public decency in public and in such a way that more than one person sees, or is at least able to see, the act. A wide definition has been applied to the term ‘public’ by the courts. It is a place where the public go, regardless of whether they have a right to be there or not. There is no need to prove any sexual motive or the intention to insult or annoy for the offence to be committed. All that needs to be established is as long as the person intended that or was reckless that the exposure might be seen by two or more persons who have not consented to see it. There is also a statutory offence of indecent exposure – section 4 of the vagrancy Act 1824 provides that “every person [who] willfully, openly, lewdly and obscenely expose[s] his person with intent to insult any female ... shall be deemed a rogue and vagabond.” This offence is punishable by three months’ imprisonment or a fine. It cannot be committed by a female.
- A person who publishes an **obscene article**⁵ whether for gain or not, or has an obscene article for publication for gain commits an offence under the Obscene Publications Act 1959. An obscene article is defined as – an article whose “effect or (where the article comprises two or more distinct items) the effect of any one of its items is, if taken as a whole, such as to tend to deprave and corrupt persons who are likely, having regard to all relevant circumstances, to read, see or hear the matter contained or embodied in it”. An ‘article’ includes any description of article containing or embodying matter to be read or looked at or both, any sound record, and any film or other record of or a picture or pictures”. An obscene publication offence is not necessarily confined to matters of ‘sexual depravity’, it could involve a publication which encourages certain sections of the community to experiment with dangerous substances (for example, particularly harmful drugs) etc. There are two known defences – the defendant had no reasonable cause to believe the article to be obscene and the publication was for the public good on the ground that it is in the interests of science, literature, art or learning, or of other objects of general concern. This is however not a *carte blanche* for researchers to publish ‘obscene’ articles. Opinions of experts as to the literary, artistic, scientific or other merits of an article may be required by the court and this opinion may not always support your cause. This is not an easy defence to raise, researchers beware!
- Other offences involving **obscene publications** include:
 - (a) obscene libel
 - (b) sending indecent or obscene matter by post
 - (c) presenting or directing an obscene performance in a play, unless it is in the public good

⁵ In reality, prosecutions are rare.

(d) indecent displays

- A researcher should also take care when using **computing systems** belonging to a third party. Under the Computer Misuse Act 1990, it is an offence to gain or attempt to gain access to program or data held in a computer which is not authorized as long as the person is aware that he is so doing or attempting. This offence does not only apply to hackers but also to researchers accessing files from a subject's computer database. Authorization must be sought. General authorisation is probably insufficient – the files you wish to access should be specified and clear authorisation (preferably in writing) should be obtained to avoid any dispute as to what was agreed and what was not between researcher and subject.
- Within the context of Diversity and Equality, researchers must take due care not to wittingly or unwittingly discriminate on grounds of race, colour, ethnic or national origin, citizenship, asylum or refugee status, socio-economic groups, gender, age, disability, sexual orientation, transgender and gender reassignment, family responsibilities, religion or belief and political beliefs. The University is opposed to discrimination based on human attributes and values listed above and will take appropriate disciplinary and/or legal action if discrimination occurs.
- A researcher should also take care when using **computing systems** belonging to a third party. Under the Computer Misuse Act 1990, it is an offence to gain or attempt to gain access to program or data held in a computer which is not authorized as long as the person is aware that he is so doing or attempting. This offence does not only apply to hackers but also to researchers accessing files from a subject's computer database. Authorization must be sought. General authorisation is probably insufficient – the files you wish to access should be specified and clear authorisation (preferably in writing) should be obtained to avoid any dispute as to what was agreed and what was not between researcher and subject.

1.7 Civil Law Duties Owed to your Human Subject

- The researcher owes a **duty of care** to his or her human subject. Reasonableness is not a subjective test. This means that just because you, the researcher, think your actions are reasonable does not necessarily mean that you are, in fact and in law, acting reasonably. One good gauge of reasonableness is the norms and conventions accepted by your research fraternity or community as being reasonable. Ensure therefore that your methods are compliant with standards laid down by your peers. This duty of care applies not only during the course of your research, but continues as long as your human subject remains a 'neighbour'. A neighbour is a person who, it is reasonably foreseeable, will suffer harm as result of your breach of duty. For example, long after you have completed your research, if the sensitive data you have collected of your subject is lost through your negligence and this causes harm or loss to him or her, you would be held liable.
- You should note that the law expects you to take your 'victim' as you find him or her. This is generally known as the 'egg shell skull' rule, that is to say, if you have breached your duty of care but given the unusual and sensitive nature of **the subject's physical or personal condition**, the damage is far worse than would normally be the case, you are liable to that extent. For example, if you fail to take care when administering a test drug to your subject. Under normal circumstances, some pain would be caused, as a result, to the subject. However, your subject is particularly sensitive to the drug and suffers very severe pain. You are liable for that pain even though another subject might only suffer minor pain.
- As a researcher, especially if you are in the professions, it is not unlikely that your **research findings** might be sought after by a third party as professional or expert advice. The law imposes a duty on advisors or persons holding themselves out as

advisors liable for the advice they give. If the following conditions are met, you could be liable for negligent misstatements:

- your advice is sought for a purpose (this does not need to be direct face-to-face consultation – if, for example, you have a web site offering ‘advice’ or ‘tips’ that could suffice);
 - you know that your advice is likely to be communicated to the person seeking your advice or a class of persons of which that person belongs (for example, you offer advice to a group who have AIDS, who are members of your web based newsgroup or a forum you are addressing);
 - you know that your advice is likely to be acted upon;
 - your ‘subject’ acts on your advice and suffers loss or damage;
 - A researcher is however not liable for statements made in his or her published works even if they are clearly erroneous. The law only makes the advisor liable when a ‘particular transaction’ is involved (provided the above criteria are met). In order to protect yourself, always add a disclaimer to any ‘advice’ you dispense, especially, when the advice is sought because of your expertise or professional standing but that disclaimer must be reasonable.
- The publication of research findings might run foul of the laws of **defamation**. Defamation is defined as the publication of untrue and unwarranted statements about an individual which tend to lower that person’s standing in the eyes of right thinking members of society. Not only are private individuals protected but companies or other business entities where it could be demonstrated that their trading reputation has been damaged by the false and unwarranted statement. The **processing of data** is subject to the Data Protection Act [1998]. The following are the so-called data protection principles laid down under the Act. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the following conditions is met:
 - the subject has given consent to the processing;
 - the processing is necessary because;
 - it is to facilitate the performance of a contract of which the subject is a party;
 - it is to comply with any legal obligation;
 - it is to protect the vital interests of the subject;
 - it is for the administration of justice;
 - it is for the exercise of any government functions;
 - it is for the exercise of any other functions of a public nature taken for the public interest by any person;
 - the personal data obtained must refer specifically to one or more specified purposes and shall not be processed in any manner incompatible with that purpose of those purposes;
 - the personal data obtained shall not be excessive in relation to the purpose/s as specified;
 - personal data shall be accurate and where necessary, kept up to date;
 - personal data processed for purpose/s specified shall not be kept for longer than is necessary for that purpose or those purposes;
 - personal data shall be processed in accordance with the rights of the subject as provided for in the Act;
 - appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data;
 - personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the personal data rights and freedoms of data subjects.

There are also special rules relating to the processing of sensitive data, i.e. data which relates to the racial or ethnic origin of the subject, their disability, their sexuality, their citizenship, asylum, or refugee status, their religion or belief, their political beliefs,

membership of a trade union, physical or mental health, sexual life, criminal record etc.

It is clearly outside the remit of this handbook to offer specific and detailed advice of data protection laws. Any researcher who could be potentially affected should consult the relevant individuals and committees in the university. It would also be beneficial for the researcher to have a copy of the Data Protection Act [1998] in hand. The Act can be downloaded free of charge from www.hmsso.gov.uk.

- 1.8 The substantial or wholesale reproduction, adaptation or translation of works belonging to your subject without proper authorisation could be in breach of copyright law. Do not imagine that your subject must register his or her work with some agency before he or she could claim copyright. There is no such requirement at law. As long as the work is original and it is an “artistic, literary, musical or dramatic” work, it would be protected. If the researcher is to publish in his own work, works made by his subjects or other third parties, he or she must be careful to ensure that copyright law is not being infringed. It has been held that even the mere reproduction of a photograph, albeit in a smaller size and on a different medium, could constitute a breach of copyright as long as the photograph had been taken with skill and is original. Researchers, especially those in the arts and social sciences, are known to reproduce without clear, unambiguous authorisation, materials produced by their subjects in research publication. Such a wholesale reproduction can be in breach.

Some examples of possible breaches

- reproduction of a picture drawn by your subject;
- translation of a Spanish poem written by your human subject;
- copying and adapting a software program written by your human subject;
- reproducing a photograph taken by your subject and placing it on your webpage as an icon without consent or licence.

- 1.9 As far as contractual duties are concerned, please ensure that any contract (whether express or implied, oral or in writing) you intend to make with persons associated with your research is discussed with an appropriately qualified person in the University. Make sure you understand the terms of your own contract of employment before embarking on any particular research project.

CAVEAT: THIS IS NOT A COMPREHENSIVE LIST OF LEGAL DUTIES TO WHICH YOU ARE SUBJECT. ANY QUERY SHOULD BE DIRECTED AT THE APPROPRIATE PERSON/ COMMITTEE.

APPENDIX 2: FURTHER REFERENCES AND BACKGROUND

FURTHER REFERENCES

Professional associations' guidelines/Government and EU publications on ethical research and research committees:

The British Educational Research Association (2004) *Revised ethical guidelines for education research*. Nottingham: BERA Publications.

British Psychological Society (2006) *Code of conduct, ethical principles and guidelines*. Leicester: British Psychological Society.

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MNRS (2002) *Guidelines for scientific integrity*. Colorado: Midwest Nursing Research Society.

Office of Human Subjects Research (National Institutes of Health)

(2005) 45 CFR 46 *Protection of human subjects*

(2004) *Guidelines for conduct of research involving human subjects at NIH*

(1979) *The Belmont Report*

(1949) *Nuremberg Code*

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**Buchanan, Elizabeth A. (ed). (2003). *Readings in virtual research ethics: issues and controversies.* Hershey, PA: Idea Group U.S.

Campbell, A., Gillett, G., and Jones, G. (2005) *Medical Ethics.* Oxford: Oxford University Press.

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Dench, Sally. (2003) *An EU code of ethics for socio-economic research.* Brighton: Institute for Employment Studies.

**Doyal, L. & Tobias, J. (2000) *Informed consent in medical research.* London: BMJ Books.

**Eckstein, Sue (ed). (2003) *Manual for research ethics committees: Centre of Medical Law and Ethics, King's College London.* Cambridge: Cambridge University Press.

Faulkner, Alison. (2005) *The ethics of survivor research.* Bristol: Policy Press.

Foster, Claire. (2001) *The ethics of medical research on humans.* Cambridge: Cambridge University Press.

**Gregory, Ian (2003) *Ethics and research.* London: Continuum International Publishing Group.

**Hay, Ian & Israel, Mark (2006) *Research ethics for social scientists.* London: Sage.

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Useful websites

Association of the British Pharmaceutical Industry
<http://www.abpi.org.uk>

Association of Clinical Research Organizations
<http://www.acrohealth.org/>

Association of Directors of Social Services Research Group
<http://www.adss.org.uk/research.shtml>

Biotechnology and Biological Sciences Research Council (BBSRC)
<http://www.bbsrc.ac.uk>

British Association of Social Workers

<http://www.basw.co.uk>

British Psychological Society

<http://www.bps.org>

British Sociological Association

<http://www.britsoc.org.uk>

Biotechnical and Biological Sciences Research Council (BBSRC)

<http://www.bbsrc.ac.uk>

British Association of Social Workers

<http://basw.org>

British Psychological Society

<http://www.bps.org.uk>

British Sociological Association

<http://www.britsoc.co.uk>

Bulletin of Medical Ethics

<http://www.bullmedeth.info/current>

The Chartered Society of Physiotherapy

<http://www.csp.org.uk>

Council of Europe Treaty Office

<http://conventions.coe.int>

Directgov

<http://www.direct.gov.uk>

Economic and Social Research Council (ESRC)

<http://www.esrc.ac.uk>

Engineering and Physical Research Sciences Research Council (EPSRC)

<http://www.esprc.ac.uk>

Office of Public Sector Information

<http://www.opsi.gov.uk>

Health & Safety Executive (HSE)

<http://www.hse.gov.uk>

Higher Educational and Research Opportunities (HERO)

<http://www.hero.ac.uk>

International Conference on Harmonisation of Technical Requirements for registration of Pharmaceuticals for Human Use (ICH).

<http://www.ich.org>

The Institute for Social Research

<http://www.soc.surrey.ac.uk>

Medical Research Council)

<http://www.mrc.ac.uk>

New Scientist

<http://www.newscientist.com>

Nuffield Council on Bioethics

<http://www.nuffieldbioethics.org>

Patient Information Advisory Group (PIAG)
<http://www.advisorybodies.doh.gov.uk/PIAG/>

Qualidata: Qualitative Data Archive Resource Centre
<http://www.esds.ac.uk/qualidata>

Royal College of Nursing Research and Development Co-ordinating Centre
<http://www.man.ac.uk/rcn/>

Scottish Office
<http://www.scotland.gov.uk>

The Social Research Association
<http://www.the-sra.org.uk>

Social Services Research Group
<http://www.ssr.org.uk>

UK Data Archive
<http://www.data-archive.ac.uk>

World Health Organisation
<http://www.who.ch>