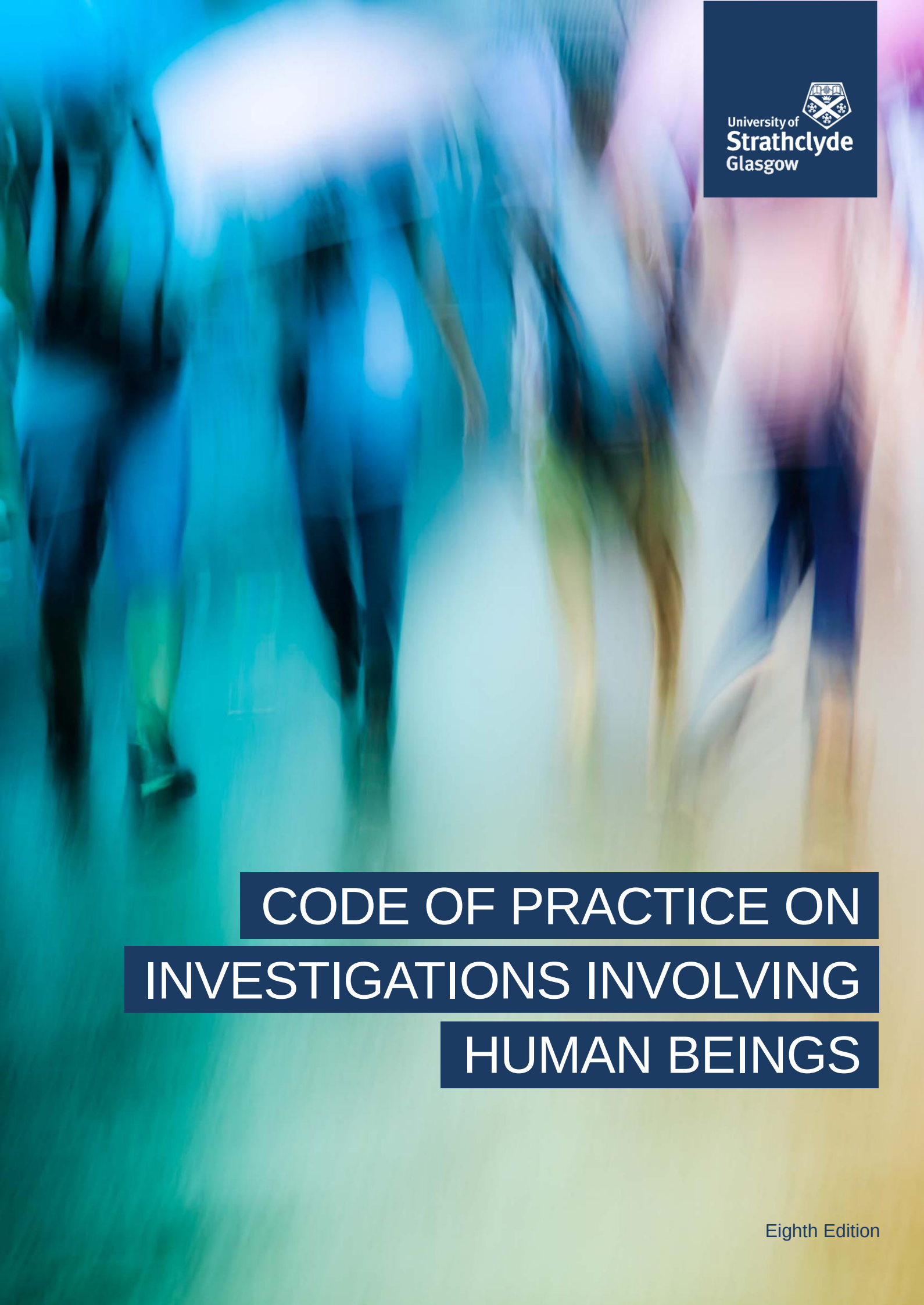

University of Strathclyde Glasgow

CODE OF PRACTICE ON INVESTIGATIONS INVOLVING HUMAN BEINGS

Eighth Edition

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Introduction

Investigations involving human beings as participants are undertaken in this University in the course of teaching and research. The University seeks to ensure that the conduct of all its staff and students carrying out such work, whether biological, psychological or sociological, conforms to standards set by professional bodies, and is known to do so. The University Ethics Committee, with its associated Departmental/School Ethics Committees, has been established to consider general ethical issues relating to the teaching and research of the University which involve investigations on human beings. It aims to provide impartial advice to participants and investigators and to protect the dignity, rights, safety and well-being of all actual and potential participants. In carrying out this role it is the body responsible for giving ethical approval for investigations involving human participants. Ethical approval is required before any such investigation can start.

The guidelines given in this document describe the overall principles and procedures by which the University makes ethical judgements on teaching and research investigations that involve human beings as participants. In applying these principles a balance has to be found. On the one hand the University requires that appropriate safeguards are in place, but on the other hand it does not want to impose unnecessary regulatory barriers that would prevent good teaching and research from taking place. The two major factors influencing this balance are risk and complexity: when the investigation involves a higher level of risk for a participant, or requires that the participant understand complex issues before giving informed consent (judged in both cases from the point of view of the participant), then there is a greater procedural burden on the investigator. The investigator has to establish that reasonable steps have been taken to mitigate risks, and that the residual risks are justified in terms of advances to human knowledge that the project will bring. Where participants have to consider complex issues in giving consent then the investigator has to ensure that information and time is given so that participants can properly reflect before giving their consent. In less complex cases verbal information and implied consent may be appropriate. It is the role of the University ethics committees to make such judgements.

In parallel with ethical approval, management risk and sponsorship are assessed. The sponsor of an investigation is the organisation that takes ultimate responsibility for that investigation – this is normally the University of Strathclyde, the lead University in a multi-institution project, the NHS, or the financial sponsor. All investigations requiring ethical approval must have an identified Sponsor. You must not start work on an investigation until you have a formal statement from the designated Sponsor confirming that sponsorship is in place. If your research requires a Sponsor you must not start work on the project until you have a formal letter/statement from the designated Sponsor. Management risk assessment is one of the requirements of the University's insurance cover in order to be able to demonstrate proper management of that investigation.

This Code of Practice was developed by the University Ethics Committee and Research & Knowledge Exchange Services (RKES). It was first published in March 2008.

1. General Scope

The Code covers:

- all investigations conducted by University staff and students involving human beings, whether for research, teaching, student projects, or other educational purposes, and using any type of research methodology;
- all investigations conducted on University property, through the University, or under the auspices of the University (including on sites external to the University and involving investigators from outside the University), that involve human beings as participants, including investigations which have been transferred from other organisations;
- collaborative investigations involving human participants carried out by University staff and students working with investigators who are not staff or students of the University, including data analysis where the data has been obtained by a collaborating body.

All University staff, associated staff, registered students and other investigators involved in University-related investigations are obliged to follow this Code of Practice.

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2. Exclusions from the Code

The Code does not apply to:

- procedures undertaken as part of routine patient-care: advice should be sought from the relevant NHS body
- research which involves only working from historical and literary databases and documents
- consultation with colleagues, experts or other stakeholders about the preparation or progress of an investigation, where those people do not contribute to the actual findings
- work which is part of routine practices in professional contexts or service evaluation (unless otherwise provided).

A service evaluation is:

- designed and conducted solely to define or judge a service
- designed to answer the question - 'What standard does this service achieve?'
- usually involves analysis of existing data but may include administration of a simple interview or questionnaire.

If you are in doubt as to whether your investigation is a service evaluation, please seek advice from your Departmental/School Ethics Committee in the first instance or from the Secretariat for the University Ethics Committee (ethics@strath.ac.uk).

3. Ethical and legal principles

3.1. Compliance with ethical principles, codes and Law

All investigations on or involving human participants must comply with:

- rules in this Code of Practice;
- all ethical principles and relevant codes and guidance developed by professional and international bodies and research councils;
- legislation and legal rules. The applicable law is that of the place or places where any aspect of the project is carried out, including of any place where the data are analysed. Where particular rules of law relate to the provisions in this Code of Practice, they are the rules of the Law of Scotland. These, therefore, are not necessarily applicable to other jurisdictions.

Introduction

3.2. General ethical principles

For all investigations covered by this Code, approval must be given by the relevant Ethics Committee (i.e. either the University Ethics Committee, the Departmental/School Ethics Committee or other ethics committee as appropriate) before the work may commence. For investigations involving the NHS, ethical approval must be sought from the relevant NHS Research Ethics Committee. Please note:

- there is an obligation on all investigators to protect participants, and potential participants, from possible harm and to preserve their dignity and rights.
- investigations should not involve any significant risk to the physical or mental well-being of the participants.
- confidentiality and privacy of participants must be maintained.
- an appropriate person (the Chief Investigator, who must be a Grade 7 or above member of staff, or equivalent) must take responsibility for the investigation; in particular, in the case of student investigations, the student's supervisor is responsible for the investigation and must act as Chief Investigator.
- transparency and openness including accurate reporting of data.
- investigations which duplicate other work unnecessarily or which are not of sufficient quality to make a useful contribution to existing knowledge are in themselves unethical.
- investigators should justify the number of participants chosen for each study.
- insurance cover may be invalidated if an investigation commences before ethical approval (as required by this Code of Practice or by other legislation/guidelines) has been obtained.

3.3. Ethics and Law

Legal rules affect the following aspects of an investigation, in particular:

- consent by or on behalf of participants in an investigation
- protecting a person's right to autonomy and dignity, including, but not confined to, bodily integrity, privacy and confidentiality
- protecting a person's property or his/her right to control property, including but not confined to rights of people who are not participants, e.g. to determine who comes onto their property
- a person's rights arising from adverse events such as personal injury or illness caused
- particular contexts, where legislation provides a special additional set of rules, including but not confined to the legislation relating to children and young persons, and legislation relating to adults with cognitive impairment
- the processing and storing of personal data, in particular provisions of the Data Protection Act 1998 and associated regulations
- a person's rights to access information under the Freedom of Information (Scotland) Act 2002
- use of human tissue obtained from deceased persons [Human Tissue (Scotland) Act 2006 and the Anatomy Act (1984)].

SECTION A: Ethics Committees at the University

1. University Ethics Committee

1.1 Purpose of the University Ethics Committee

The University Ethics Committee (UEC) is a sub-committee of the Research & Knowledge Exchange Committee (RKEC). Its remit is:

- to devise and submit for approval by RKEC a University Code of Practice on investigations on human beings, to keep the Code under review and to recommend such modifications as from time to time are deemed necessary
- to implement the current edition of the Code and to amend and update the Annexes as appropriate
- to consider whether ethical approval should be granted for applications submitted to it for ethical review, applying appropriate skill and care in doing so
- to continue to monitor investigations for which approval has been given, and receive reports on their outcomes
- to consider and promote the understanding of general ethical issues relating to the teaching and research of the University which involve investigations on human participants and to provide impartial advice to staff and students of the University who undertake or who participate in such investigations on the ethical considerations involved
- to protect the dignity, rights, safety and well-being of all actual and potential participants involved in such investigations
- to be available to give advice and to liaise with external bodies, such as relevant NHS Research Ethics Committees and national university research ethics committee organisations, on ethical matters as appropriate
- to monitor the work of Departmental/School Ethics Committees
- to report annually to RKEC.

1.2 Composition of the University Ethics Committee

The composition of the UEC is such that it comprises a pool of up to 18 members representing a broad range of experience and expertise and normally including a member with academic training or expertise in ethics, a lawyer and a medically qualified person. There is a quorum of seven members for each meeting. The UEC comprises:

- up to 12 internal members from members of staff within the University, one of whom shall be the Convener
- up to three external members who are not employees of the University
- up to three lay members who are independent of the University and have no previous experience in carrying out investigations involving human participants.

Members of the UEC will normally be appointed for three years at a time, and may be reappointed for subsequent years.

The Convener of the UEC is appointed by the Senior Officer with responsibility for the UEC and the Director of Research & Knowledge Exchange Services (RKES). Up to four Vice Conveners may also be appointed. The Convener and Vice Conveners are appointed from amongst the members of the UEC, for a maximum period of six years, and normally for three years in the first instance. The Convener and Vice Conveners may act on behalf of the UEC and may approve investigations between meetings, subject to agreement of the UEC and report back on any action taken. A Vice Convener may act in the absence of the Convener and as otherwise delegated by the UEC. There is no automatic progression from Vice Convener to Convener.

Additionally, at the Convener's discretion, the UEC may seek expert advice and guidance from named members of staff or other independent experts on a range of matters as and when required.

SECTION A: Ethics Committees at the University

1.3 Declaration of interests

All members of the UEC, and anyone asked to provide expert advice to the UEC, who have an interest which may affect their consideration of a particular application or matter are required to declare that interest and, if necessary, should temporarily withdraw from the meeting for consideration of that proposal. The University's Code of Practice on Conflicts of Interest (www.strath.ac.uk/media/ps/cs/gmap/academicaffairs/publications/Code_of_Practice_-_Conflicts_of_Interest.pdf) must also be adhered to.

1.4 Confidentiality

All members of the UEC are expected to respect the confidentiality of the UEC's business. Lay and external members are required to sign a confidentiality statement on their appointment to the UEC. This statement confirms that they will respect the confidentiality of the UEC's business in relation to information of a commercially sensitive nature or relating to intellectual property rights.

2. Departmental/School Ethics Committees

2.1. Purpose of Departmental/School Ethics Committees

Every department which undertakes projects which fall within the remit of this Code of Practice should establish a Departmental Ethics Committee (DEC) or a School Ethics Committee (SEC). The DEC/SEC should consider all applications for ethical approval within the department that do not fall within the criteria for consideration by the UEC, and any matter referred to it by the UEC, applying appropriate care and skill in doing so.

- DEC/SECs shall meet as often as required to consider applications made to them. Investigators who have submitted proposals for consideration shall be informed of the DEC/SEC's decision by the secretary to the DEC/SEC.
- DEC/SECs shall report annually to the UEC on their work.
- DEC/SECs should consider preparing guidance and procedures relevant to research and related activities in their domain drawing on this Code of Practice and relevant professional standards.

There may be instances when it would be appropriate to establish joint Departmental/School Ethics Committees, for example, smaller departments might find it advantageous to work within a larger grouping where expertise and responsibilities can be shared.

2.2 Composition of Departmental/School Ethics Committees

The composition of the DEC/SECs is such that they shall comprise a minimum of two members of staff from the Department(s)/School concerned and may also include either a member of staff from another department or an external member. The quorum for DEC/SECs is two, and it is essential that no member of staff acts as a member of the committee when it is considering an application that he or she has submitted to it. One of the members of the DEC/SEC must act as Convener of the DEC/SEC and may also act as Secretary to the DEC/SEC, or another person may act as secretary. The secretary has the obligation to provide further information to investigators as necessary in formulating applications, and will be responsible for informing them of the decision of the DEC/SEC, and where the application is rejected, or the DEC/SEC requires it to be amended, the reasons for that decision. The Convener and/or Secretary of the DEC/SEC are responsible for maintaining a record of all submissions made to it and the decisions reached.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

The following section contains a step-by-step guide to the procedures to be followed - see also the flow charts overleaf.

Chief Investigators should ascertain whether the application falls within the remit of the UEC or the DEC/SEC – see Section B1 and B2 (refer to pages 10-12).

Investigators must have all relevant ethical approval, insurance cover, and sponsorship approval in place before the study can begin.

University Ethics Committee

- The Chief Investigator (CI) should complete the University application form (available online at www.strath.ac.uk/ethics) and obtain the signature of the Head of Department. If the CI or co-investigator is the Head of Department then the application must be signed by the Dean. or if the study involves the NHS then an IRAS application form has to be completed – this can be downloaded from the IRAS website – www.myresearchproject.org.uk/.
- The completed application form should be sent to ethics@strath.ac.uk together with all accompanying documentation, e.g. participant information sheets and consent forms, by the deadline set by UEC. Templates for the participant information sheet and consent form and the deadlines for submitting applications can be found on the ethics website. RKES will process for sponsorship and management approval and inform the CI of the decision.
- The UEC will consider the application and may approve it; or may seek further information; or may not approve it. The Chief Investigator will be informed of the outcome of UEC's deliberations.
- If the application is approved, then confirmation of insurance cover will also be provided to the CI.
- If further information is required the CI will be told what this is. The UEC may decide that the further information has to go back to UEC for consideration and approval, or the Convener/Vice- Convener may be delegated authority to approve it on behalf of Committee.
- The CI will be told of the outcome.
- The CI must ensure that final revisions have been communicated to UEC within one year of initial review by UEC of the application for ethical approval. Failure to do so will mean that a new application must be submitted.

Departmental/School Ethics Committee

- The Chief Investigator (CI) should complete the University application form (as above).
- If study involves the NHS or has external funding then the completed form has to be sent to ethics@strath.ac.uk (together with all accompanying documentation). RKES will process for sponsorship and management decision, as well as confirmation of insurance cover. The CI will be informed as to the decision.
- At the same time the completed form can be sent to the department for consideration by the DEC/SEC.
- If the study does not involve the NHS and has no external funding then the Head of Department may take the decision on sponsorship and management and can approve the study if satisfied.
- The DEC/SEC will consider the ethical dimension of the study and may approve it; or seek further information; or may not approve it. The DEC/SEC may have set deadlines for applications and investigators should be aware of these. The DEC/SEC will notify the CI of the outcome of its deliberations.
- If further information is required the CI will be told what is required.
- Once approved, the DEC/SEC will notify the CI accordingly.

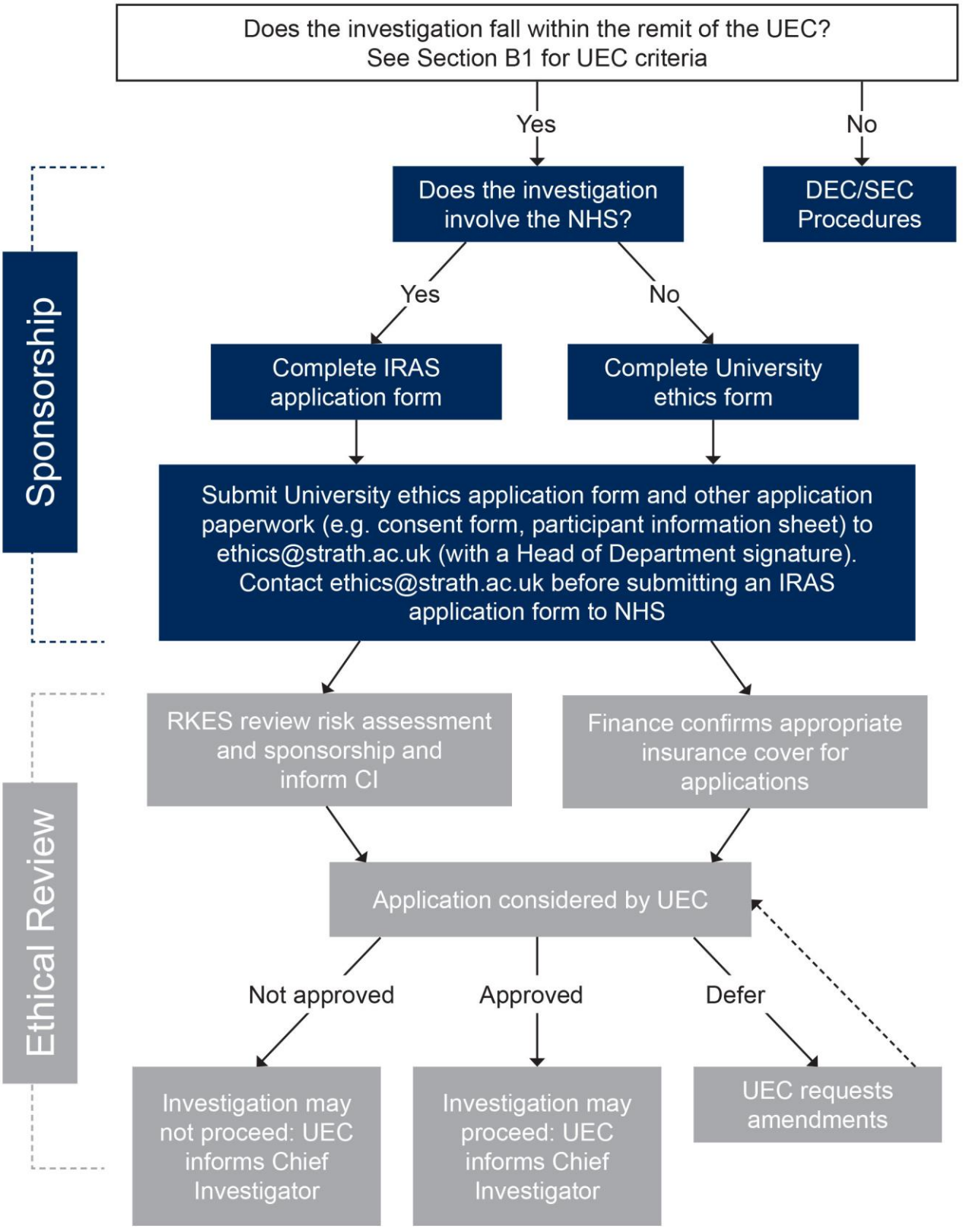
HaSS applications

There are different processes and procedures for HaSS applications to the UEC and their SEC, please contact the HaSS Research and Knowledge Exchange support team (RaKET) by email on hass-rke@strath.

ac.uk or refer to www.strath.ac.uk/ethics for guidance.

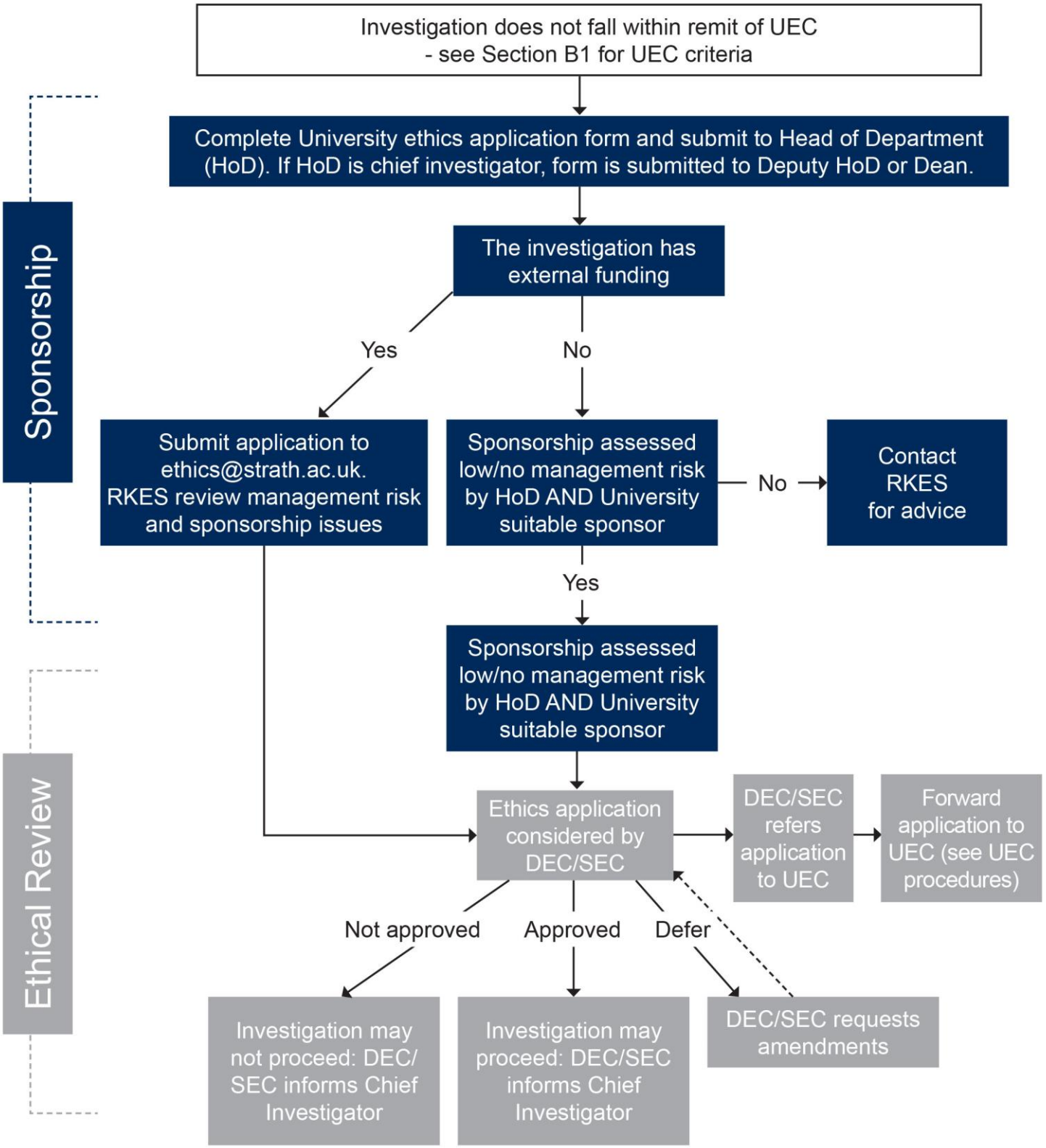
SECTION B: Principles and Procedures for Obtaining Ethical Approval

Procedures for ethics applications for investigations involving human beings:
Submission to University Ethics Committee



SECTION B: Principles and Procedures for Obtaining Ethical Approval

Procedures for ethics applications for investigations involving human beings: submission to Departmental/School Ethics Committee



SECTION B: Principles and Procedures for Obtaining Ethical Approval

1. Projects which require consideration by the UEC

Investigations governed by the Code that involve any of the following types of projects or participants must be submitted to the UEC for prior approval:

1.1. Project considerations

Studies must be considered by the UEC if they involve:

i. any significant harm or serious discomfort of a physical or psychological nature
ii. an extensive degree or duration of exercise or physical exertion beyond that to which all the participants are habitually accustomed
iii. the collection and/or use of human biological tissue and/or fluid
iv. the use of an invasive procedure
v. the isolation and profiling/typing of an individual's DNA
vi. intentional deception of participants where the true nature of the study is such that there is a possibility of causing physical or psychological harm or distress
vii. activity which can be classed as a clinical trial or any type of investigation of a pharmaceutical drug, medical procedure or medical device (see Annex 7 for the definition of 'medical device')
viii. the administration or discontinuation of pharmaceutical drugs, liquids or other substances not normally consumed by the general population
ix. a situation where highly personal, intimate or other private or confidential information of a personal nature is sought
x. the NHS, where the criteria in Section B9 (below) apply. Check that NHS approval is needed – use of NHS staff and premises may not in themselves be criteria for requirement of NHS approval.

1.2 Participant considerations

Studies must be considered by the UEC if they involve a group of participants who are in a situation of special vulnerability (e.g. women of childbearing potential where the investigation might carry any risk to pregnancy orto a foetus, or persons with addictions). This may include those who:

i. are severely ill or have a terminal illness
ii. are prisoners or young offenders, or are awaiting trial for a crime or offence that is relevant to the project
iii. are potentially subject to coercive measures by government, such as detention, restrictions on movement, deportation or repatriation
iv. live in or are connected to an institutional environment;
v. have a physical disability or a chronic physical condition relevant to the subject of the investigation and for whom participation in the investigation may pose a risk to their wellbeing
vi. are unable to consent for themselves or have significant learning difficulties and/or serious mental health issues and/or cognitive impairment of a nature and extent that would affect their ability to give informed voluntary consent (see sections 4.3.7 and 4.3.8). Not all projects where children under the age of 12 are participants need to be submitted to the UEC. Unless another of the conditions in 1.1 or 1.2 above applies, projects where children under the age of 12 are participants may be submitted to the DEC/SEC.

If you require any further advice on this please contact ethics@strath.ac.uk.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

2. Projects which may be considered by a Departmental/School Ethics Committee

Where it is clear that a study does not involve any of the criteria which require it to be referred to the UEC, or when the UEC has delegated authority, then DEC/SECs can approve investigations involving human participants. The DEC/SEC may, where appropriate, consider generic framework applications, see Section B3 below. If a DEC/SEC has any doubts about any particular investigation it is asked to consider, or if it does not have the relevant expertise to make a determination on an application submitted to it, or if it cannot reach agreement, then this will be referred to the UEC for consideration.

3. Generic framework approvals and procedures

Three types of generic framework exist:

- groups of similar investigations or teaching exercises involving human participants
- devolvement of certain studies from the UEC to a DEC/SEC
- use of simplified approval procedures by a DEC/SEC for a class of investigations under its remit.

Such approvals last for three years.

3.1. Multistudy approval

3.1.1 Procedures and approval

It is possible to receive ethical approval for groups of similar investigations and teaching exercises by submitting an application for approval of a generic framework. Such applications should be submitted to the UEC if the multistudy application falls within the remit of the UEC (see Section B1 on page 11) or the appropriate DEC/SEC if the multistudy application does not fall within the remit of the UEC. This should be submitted using the multistudy application form (see www.strath.ac.uk/ethics) to the relevant ethics committee.

Once the UEC or DEC/SEC has granted approval of a multistudy application, each individual study that falls within this multistudy application will have ethical approval as long as it remains within the parameters of the approved multistudy application and will not need to seek individual ethical approval from the relevant ethics committee. Any study that does not fall or remain within the parameters of the framework must be approved by the relevant ethics committee before it can commence/continue. Multistudy application approval is normally for a period of three years.

Examples of when this approach may be used would be:

- where approval is required for a specific teaching exercise to be used over several years;
- where approval is required for a number of related investigations that adopt the same procedure(s), and/or use the same research materials, and/or have related objectives, over a period of years. This could apply to student dissertations.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

3.1.2 Annual monitoring

The Chief Investigator/Course Leader must keep records of the individual investigations and/or teaching exercises that have begun and that fall within the remit of the multistudy application approval in order to monitor compliance and ensure that current professional standards are being maintained. The records will include investigations/teaching exercise titles, investigators, ethics approval date, start and end dates of the project, management approval date. The DEC/SEC will report annually to the UEC on approvals of multistudy applications and the individual investigations and/or teaching exercises which fall within the multistudy application, as part of the DEC/SEC annual monitoring exercise. The CI will report annually to the UEC in relation to multistudy applications approved by the UEC, as part of the annual monitoring exercise of ongoing investigations.

3.1.3 Risk management

The University's Risk Management Framework (www.strath.ac.uk/safetyservices/riskmanagement) should be followed by the CI.

3.2 Devolvement

3.2.1 Procedures and approval

A DEC/SEC can apply to the UEC to request the UEC to devolve responsibility for ethical approval to the DEC/SEC for certain categories of investigations which would normally fall within the remit of the UEC (See Section B1 on page 11) but where the DEC/SEC considers that it has the appropriate expertise to consider such investigations. An application for devolvement should be made on the 'Request to devolve responsibility' form. The devolvement application should be sufficiently detailed to allow the UEC to make an informed decision as to whether devolvement would be appropriate.

If the UEC approves the devolvement application, the DEC/SEC must only approve investigations that clearly fall within the parameters detailed in the application form. Should the DEC/SEC have any doubt that an investigation does fall within these parameters or if the DEC/SEC is uncomfortable about granting ethical approval for any individual application then this should be referred to the UEC for consideration and approval.

3.2.2 Annual monitoring

The DEC/SEC must keep records of the individual investigations that fall within the remit of the devolvement and that it grants ethical approval for. The DEC/SEC will be required to report on these records annually to the UEC as part of the DEC/SEC annual monitoring exercise.

3.3 Simplified approval procedures

Generic frameworks may cover groups of investigations that would normally fall within the remit of the DEC/SEC, but where the DEC/SEC wishes to use a streamlined procedure. This might include forms adapted to a particular class of investigations, standardised consent forms, exclusion criteria, etc. This type of framework is approved by the DEC/SEC but is reported to UEC as part of the DEC/SEC annual monitoring exercise.

3.4 Risk management

The University's Risk Management Framework (http://www.strath.ac.uk/safetyservices/riskmanagement/) should be followed by the CI.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

4. Specific ethical principles

4.1. Suitability of investigators

4.1.1 General suitability

All investigators must have the necessary expertise and experience to carry out their role in connection with the investigation. The Committee may seek proof of training for certain procedures and may ask for a curriculum vitae (CV) to be provided. The CI has, and must accept, responsibility for the oversight and monitoring of the investigation, the work undertaken as part of the investigation, and must meet all reporting requirements, including reporting of any change of staff on the project.

4.1.2 Protection of vulnerable groups

Membership of the Protection of Vulnerable Groups (PVG) scheme is available for certain groups of people undertaking regulated work with children (a person under 18 years of age) or a protected adult (someone aged 16+ in receipt of one or more care, health or welfare service). Regulated work is defined by a set of criteria listed on the Disclosure Scotland website. If a member of staff is appointed to a role in the university which counts as regulated work, then HR will assist with an application to join the PVG scheme. However, it is current practice for data gathering as part of research activity to be considered by Disclosure Scotland as incidental to main employment duties in a university and therefore, they have not been accepting PVG applications for research purposes. Research which may have an influence on NHS service provision may be an exception to this and may be able to gain PVG scheme membership more easily. Disclosure Scotland may provide alternative types of Disclosure for some research studies (the categories are currently Basic, Standard and Enhanced). Alternatively, the University can provide a letter for gatekeeper organisations or gatekeepers within organisations stating that data gathering is not considered to be an activity which requires membership of the PVG scheme. Please contact (Lorna Dougall (l.dougall@strath.ac.uk) for further information. Applicants are advised that appropriate safeguards for the protection of participants (vulnerable or otherwise) should form part of an ethics application, where appropriate, irrespective of the status of PVG membership.

4.2 Recruitment of participants

4.2.1 General principles governing recruitment

Methods of recruitment must be consistent with the need to obtain informed consent (see below). There should be no indication, express or implied, of any expectation of an agreement to participate. Generally, no inducement should be offered to a participant or proposed participant. Any payment, other than expenses or small remuneration for time spent, must be justified.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

4.2.2 Recruitment procedure

- In all cases details of the methods proposed for the recruitment of participants must be provided in the application to the relevant Committee.
- The process of recruitment should normally be initiated via a letter, notice or, if orally, through a group approach rather than to individuals.
- Where advertising is to be used, the form of the advertisement and the publicity method(s) to be adopted for bringing it to the attention of potential participants should be stated in the application. Draft advertisements should be provided with the application for approval.
- Where it is proposed to undertake random street or doorstep surveys, telephone interviews, mail or email surveys, details of these must be included in the application.
- Investigators should justify the number of participants to be included in each investigation. For example, a calculation of the statistical power may be appropriate. If an investigation is 'underpowered' then further justification of validity should be given.
- Where the investigation involves the recruitment of non-native English speakers the Committee will wish to be clear about the inclusion/exclusion criteria for the investigation, and be assured that the information about the investigation is presented in an appropriate form and that interpreters and translators are used appropriately to the investigation. The Committee may ask for further information about the qualifications and experience of the interpreters/translators involved before approving the investigation and may request that such individuals be bound by appropriate confidentiality obligations.

4.3 Informed consent

General principle

It is a general principle that participants have to consent to take part, and consent to the use of any material or personal information. Consent should be voluntary and informed. This principle applies during the course of an investigation as well as when the participant consents to take part. In some situations (detailed at 4.3.3 below) this principle is qualified.

4.3.1 Informed consent during the investigation

Should new information relevant to voluntary consent emerge during the investigation, this information must be communicated to each participant. Where, for any reason, a participant wishes to withdraw from the investigation, or wishes to withdraw some or all of their data, that wish must be respected. Data which is held anonymously cannot be withdrawn once collected and this should be made clear to the participant in accompanying documentation. If the participant wishes it, an opportunity should be provided for him or her to discuss in private decisions relating to withdrawal.

Participants should be made aware that at no time do they have to answer any questions, or participate in any activity, that they may feel uncomfortable with. Incomplete answers may invalidate some standardised questionnaires and while participants still have the right not to answer any question, researchers may encourage participants in the written instructions to complete the entire questionnaire. However, participants must be fully informed as to the nature of the questions before beginning a questionnaire, particularly where there are any questions relating to sensitive or personal information.

SECTION B: Principles and Procedures for Obtaining Ethical Approval

4.3.2 Loss of capacity to consent during an investigation

Should a participant in the course of an investigation lose the capacity (see Section 4.3.7 below) to consent they cease to be a participant unless someone able to legally consent on their behalf does so. As 'capacity' applies to specific tasks at a specific moment in time, a person may lose capacity to consent to one part of a study while retaining capacity to consent to other parts. Similarly, capacity to consent may fluctuate across time and consent may need to be re-taken at later intervals. The mechanism and underlying rationale for assessing capacity and taking consent with any population who may have fluctuating or deteriorating capacity should be fully outlined in the application.

4.3.3 Where informed or fully informed consent is not required

It is recognised that some investigations would be invalid if the participants were to be made aware of the whole nature of the investigation or the nature of some aspects of the investigation. The general principles in such circumstances are:

- the chief investigator will have determined that alternative procedures are not available;
- that the information withheld is the minimum necessary; and
- that the likely reaction of a participant if, after taking part when told of the nature of the investigation or those aspects of it, would not cause discomfort, anger or objection.

The Committee endorses the guidance issued by the British Psychological Society in its Code of Conduct, namely:

"The withholding of information or the misleading of participants is unacceptable if the participants are typically likely to object or show unease once debriefed. Where this is in any doubt, appropriate consultation must precede the investigation. Consultation is best carried out with individuals who share the social and cultural background of the participants in the research, but the advice of ethics committees or experienced and disinterested colleagues may be sufficient. Intentional deception of the participants over the purpose and general nature of the investigation should be avoided whenever possible. Participants should never be deliberately misled without extremely strong scientific or medical justification. Even then there should be strict controls and the disinterested approval of independent advisors."

4.3.4 Information to be given to proposed participants

4.3.4.1 Information in writing – information sheet

For investigations that fall within the remit of the UEC or DEC/SEC, and more generally those in which a participant will need to reflect to make an informed decision to participate, it is normal that each proposed participant is given an information sheet. Additionally, the investigator should discuss the investigation with him or her and answer fully and informatively any questions about it. Information sheets must be submitted with the application to the relevant ethics committee for consideration and approval. A template for the Participant Information Sheet (PIS) can be found at www.strath.ac.uk/ethics.

The PIS should:

- be in a form that is readily understood by the individual proposed participant, or his/her parent or guardian, or other person legally empowered to act, where appropriate
- take account of any vulnerability of the proposed participant
- provide full, relevant details of the nature, objectives and duration of the proposed investigation
- inform proposed participants who the investigators conducting the investigation are and what their designation is, particularly if any of them are students
- detail the procedures the investigation will involve and whether any discomfort or inconvenience is likely to be caused during the investigation or afterwards

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- detail any risks to physical or psychological health that the investigation may pose
- state that the proposed participant may withdraw at any time and that in that event data arising from his or her participation will be destroyed, unless the participant specifically states at that time that the data may be retained
- state that confidentiality and anonymity will be maintained. Any waiver of confidentiality must be justified and agreed by the participant in writing. Where the investigation is one in which there is a significant likelihood that participants might disclose information relating to serious harm or immediate danger (e.g. in investigations relating to people at high risk of abuse), the circumstances in which the investigator will need to pass on information about that should be stated (see 4.5 below)
- state that data gathered will be securely stored, how long it will be retained, and that it will be used only for the investigation, or detail that it might be used to inform future investigations. If it is to be used for any other investigation, now or in the future, participants must be told and must consent to this.

4.3.4.2 Information in writing – other forms of communication

There are some situations, e.g. an investigation about a person's experience in the workplace or in a position in an organisation or body where that information is of a non-sensitive nature, the information may be communicated in the form of a letter or an email.

Investigators are encouraged to provide feedback on the outcomes of the investigation to those who participated in the investigation.

4.3.4.3 Information given orally

Where the investigation is low risk and potential participants do not have to understand complex issues, then information can be given orally if appropriate to the research method (for example, street or telephone interviews). The investigator should use a script which should address the same issues as the written information sheets, where appropriate, and include a copy of the script with the application.

4.3.5 Consent forms

Consent is given by the agreement of a person to participate in a research study. Documenting this consent provides protection for a researcher should a participant later claim that they did not wish to participate or had done so under false pretences. It also provides an additional check as to what understanding the participant has concerning the research and their involvement in it. Consequently, the University requires that documented consent be obtained wherever possible.

Consent should be obtained in an appropriate way. The mode of consent should be expressed in a way that is readily understood by the proposed participant, or his/her parent, guardian, or person legally empowered to act. The mode of form should take account of any vulnerability of the proposed participant.

Except in the circumstances detailed below every participant should sign a consent form following information being given as above within information sheets. Consent forms must be submitted with the application to the ethics committee for consideration and approval. A template for the consent form can be found on the website www.strath.ac.uk/ethics. Note that while the NHS requires the use of tick boxes or initials to each bullet point on a consent form, for research not involving the NHS, UEC recommends that a single signature at the bottom of the consent form is necessary and sufficient to give documented understanding of all the bullet points and consent to participate. The only exception to this is where some parts of the study are optional (e.g. access to medical records, audio or video recording) where a yes/no bullet point can be included (note: if audio or video recording is necessary then this should be given as a normal bullet point without a yes/no option and willingness to be recorded as part of the study should be included as an inclusion criterion).

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Potential participants should be given time to consider the information sheet if there are risks, ethical issues or other considerations which may require reflection on whether to participate or not (e.g. time commitment), and the consent form will include a statement which confirms that the participant has understood the information in the information sheet. Specific consent to audio or video recording, where this is proposed to be used, must be given.

Where samples of human biological material are to be taken the form must include consent to their use.

The Chief Investigator must retain copies of the signed consent forms for each participant.

Other forms of consent

4.3.6 Implied consent

In the circumstances described above, where information is not provided through a written sheet, consent can be given in a corresponding way – email, letter, orally, or via a check box on a webpage or questionnaire. Completing and returning a questionnaire (or pressing a 'submit' button online) may also be taken as consent. When a telephone interview is to be recorded the participant must consent and that agreement should ideally be included in the audio recording

4.3.7 Obtaining consent from participants whose cognitive ability is impaired

It should be determined by a person with appropriate expertise whether any proposed participant whose cognitive ability is impaired may lack capacity to consent. If a person with appropriate expertise is not able to confirm that a proposed participant is capable of giving informed consent then the investigator must contact a person who can act on his or her behalf (this may be a parent, someone with legal power appointed under a Welfare Power of Attorney, or a Guardian appointed under the Adults with Incapacity (Scotland) Act 2000, or a carer). This person should confirm whether or not the proposed participant is able to give informed consent, and if not will be responsible for giving, or refusing, consent. The investigator should also be clear that the participant is happy to take part in the investigation and record that in writing in an appropriate form.

If any proposed participant's cognitive ability is to an extent impaired but sufficient to understand and give consent, then consent must be obtained from him or her, and additionally the consent of any person empowered to act on his or her behalf must be obtained.

4.3.8 Obtaining consent from participants under the age of 16

Researchers recruiting participants under the age of 16 are normally expected to gain written consent from parents, or other(s) with parental responsibilities, to include their children in the study. Consent should also be obtained from the child, normally after that. Researchers may require the child's consent to be in writing (depending on the nature of the study and the age, maturity and life experience of the child) but if given orally, for example as an expression by the child that he or she is happy to participate, researchers should maintain a record showing that consent was given.

There may be circumstances where it is not possible to gain parental consent due to the nature of the study (e.g. a street interview), or situations where seeking parental consent is deemed unnecessary due to the nature of the study and the context of the child. However, even where a research question may seem entirely harmless, it may not be the case for a particular group or a particular child and any study not seeking parental consent on this ground must fully justify this approach (taking into account the standpoint of parents wishing to be involved and informed on any research involving their children and any known views of the child with respect to the question). It may be appropriate instead to obtain consent from a person who acts as a 'gatekeeper' to the child or children (e.g. a head teacher) rather than from parents but this approach must also be fully justified in the application.

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4.3.8.1 Active/passive consent of parents

It is generally expected that active (opt-in) consent will be sought unless there is sound justification for passive consent (opt-out). The decision to seek active or passive parental consent will depend on several factors including the nature of the study and views of gatekeepers and other stakeholders.

4.3.8.2 'Looked after' children

Where a child is a 'looked after' child (e.g. in residential care) the investigators must identify who has 'parental responsibilities' with respect to that child. Permission must be obtained from the appropriate person or organisation that has parental responsibilities to contact that child. In doing this, information about the nature of the investigation and its potential impact on the child should be given to that person.

If a parent has 'parental responsibilities' but in view of the best interests of the child, for instance, in the light of a background of harm to the child or breakdown of family relationships, consent should not be sought from that parent or other family member.

In all other situations the consent of the person with 'parental responsibilities' should be obtained. The investigator should also be clear that the child is happy to take part and record that in writing in an appropriate form.

4.4. Anonymity

As a general principle, participants should not be identifiable in the investigation outputs, except where they are providing information as experts and have consented to being identified. Investigators should, where possible, follow general Data Protection Act principles, in particular by either anonymising or pseudo-anonymising data as soon as possible. Section D sets out guidance in relation to the Data Protection Act 1998.

Detailed reasons should be given in the application as to why it is proposed not to follow this principle. In such a case express waiver of the principle should be included in the consent form. The waiver should be of the minimum necessary extent.

4.5. Information of criminal or other wrongful conduct

There is no general requirement to pass on information relating to criminal or other wrongful conduct. However, there are important exceptions and certain other requirements in particular contexts:

4.5.1 Criminal or other wrongful conduct by participants

- Where the investigation is of a nature that any participant will, or will be likely, to refer to things he or is doing or has done that constitute a criminal offence, the researcher should ask the participant if he or she is comfortable with revealing such information. This and the participant's response should be recorded in writing. If the participant says he or she is not comfortable, the researcher should not take any steps that will be likely to lead to the participant's revealing that information. If this entails terminating the research with that participant the investigator should avoid conveying any impression that the participant should change his or her mind. If the study involves a group setting, then the researcher should ask each participant present whether they are comfortable with having such information revealed and establish agreed rules for confidentiality. If there is an objection then the researcher must decide whether to ask the speaker not to reveal such information or to excuse the objector from the session.

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- Where, in the course of research, comments are made to the researcher concerning a third party that might be considered to be offensive or defamatory, the researcher should take particular care when considering how the results of the research are to be disseminated. Repetition of any opinion that may be considered defamatory could be subject to legal action and should be avoided and in all cases the source of any potentially controversial or defamatory opinion stemming from the research should be anonymised.
- Where the researcher identifies that the proposed research might touch upon matters that are the subject of an on-going criminal investigation, the researcher should seek guidance from the UEC before proceeding any further. In such circumstances, it is likely that the UEC will require the researcher to seek the approval of the relevant authorities before continuing with the research.
- Where a participant discloses that someone is being physically or psychologically harmed, by him or her, or is at risk of immediate harm or danger (whether physical, psychological or otherwise) by him or her, the investigator should terminate the interview or other interaction with the participant, tell the participant that he or she needs to report the information, discuss with the participant how he or she can best be supported in the circumstances, and should report that information to the UEC. Where the researcher believes that the participant may cause imminent harm to someone then they should report this to the police as soon as possible and in addition, inform the UEC.
- Where a participant discloses that he or she is engaged in other exceptionally serious criminal activities, for instance, large scale fraud or blackmail, the investigator should, when such information is revealed, inform the participant that he or she needs to terminate the research with them, and seek guidance from the UEC.

4.5.2 Criminal or wrongful conduct by persons other than participants

- Where a participant discloses that he or she has been harmed or is at risk of immediate harm or danger (whether physical, psychological or otherwise), the investigator should pass on that information to a person who can give support to the participant. Before doing this the investigator should discuss this with the participant, and discuss how he or she can best be involved, with support, in the circumstances.
- Where a participant discloses that someone else is in immediate physical or psychological danger from another person or is being seriously physically or psychologically harmed by such as person, the investigator should report that to the police and, if appropriate, someone who could help that person, and discuss how the participant can be best supported in the circumstances. They should also inform the UEC as soon as possible.
- Where a participant discloses he or she or someone else is a victim of or is immediately threatened with being a victim of exceptionally serious crime in other ways such as through large scale fraud or blackmail, and which has not been reported to the police. The investigator should, inform the participant that he or she needs to terminate the research with them, and seek guidance from the UEC.

4.6 Biological and medical investigations and previous medical history

4.6.1 Donation of samples etc

Where any biological sample is taken from a participant, the consent form should include wording that that material becomes the property of the University (for background information see Annex 5).

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4.6.2 Previous medical history

Only where appropriate, should participants be asked about their previous medical history. Where the investigation involves an invasive procedure or may have a potential impact on the mental or physical health of a participant who is undergoing treatment, it is good practice to send a letter to the participant's GP or other medical adviser. This may only be done with the participant's permission.

In certain circumstances, the ethics committee or the University's Insurers may require that a person with suitable medical qualifications should be responsible for an investigation or in attendance when certain procedures are carried out, or that facilities for emergency medical care should be at hand. It may require in certain cases that participants should be medically screened before taking part in an investigation (e.g. via ECG). Where appropriate, safeguards regarding communicable diseases should be taken to protect the participant, the investigator and others involved in the work.

4.7. Medical records and other records relating to care, education, etc

The general principle is that participants' records (for example medical records, social work or school records) are not accessed as they are confidential.

If it is intended to access participants' records detailed reasons should be given in the application as to why it is proposed not to follow this principle. In such a case an express permission to access records should be included in the consent form. The permission should be of the minimum necessary extent. A form for obtaining permission from the person or body holding the records should also be included in the ethics application.

4.8 Research in relation to deceased persons

Wherever research is carried out that involves an investigation of any aspect of a person who is deceased, the research should respect the dignity of that deceased person and of family members.

4.9 Cadaveric tissue

The Code of Practice deals primarily with the ethical considerations involving living human beings. However, for some research, it is necessary to work with whole, or parts of, deceased bodies. There are two aspects to working with deceased human beings. First, the investigator must ensure that he/she is legally allowed to work with such tissue, and secondly, there is the issue of the ethical considerations of working with such tissue. The law in Scotland is different to that of the rest of the UK. To work with cadaveric tissue you must either hold an appropriate licence from Her Majesty's Inspector for Anatomy in Scotland, or work in collaboration with a licence holder. The major ethical issue is one of informed consent, agreed at the time of body donation. All research involving cadaveric tissue should be reviewed by the UEC unless this responsibility has been devolved to a DEC/SEC. See Annex 6 for more detail.

All research involving human tissue (defined as any solid or fluid containing human cells, which includes urine) must be approved by the UEC, or a DEC with appropriate devolved powers. All human tissue obtained directly from volunteers must be obtained through appropriately trained staff. The ethics application must make it clear the level of training of the research group in this regard. Tissue may also be obtained via regulated tissue banks, for example the NHSGGC Bio-repository, which have generic NHS approval for research purposes. These 'biobanks' will review an application for tissue, and once approved, they will release anonymous tissue to appropriate researchers. Whilst an IRAS (NHS) ethics application is not required in this case, researchers must still complete a UEC application.

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4.10 Exposure to risk, including location of investigations

The places where investigations are to be undertaken must be appropriate to the type of study and the risks involved. This includes consideration of the investigator – who should not be placed in a vulnerable situation – as well as the participants. The ethics committee reserves the right to visit and inspect any such facility. Within the University all research and teaching investigations involving humans should be carried out in line with the University's Occupational Health and Safety Policy and Regulations. For any investigations being conducted elsewhere investigators will be required to comply with the Health and Safety rules in place at that site. Where research takes place at premises other than the University's premises, the Chief Investigator must ensure that suitable Health and Safety arrangements are in place before research commences. Under legislation any premises used for conducting clinical trial work will be subject to good clinical practice and, where appropriate, good manufacturing practice inspections. These will be conducted under the auspices of the MHRA and will incur a fee.

5. Approval procedures: University Ethics Committee

The UEC meets on a monthly basis to consider applications submitted to it by the submission deadline published on the University's website (www.strath.ac.uk/ethics). From the time of receipt of an application, the Committee will usually make its decision within 60 days. However, if the Committee seeks further information from the investigators then the timescale is suspended until the Committee is satisfied that all its points of concern have been answered. The UEC Secretariat will communicate this decision to the Chief Investigator in writing as soon as practicable after the decision is made.

5.1 Powers of the Committee in considering applications

The Committee may:

- approve the application
- approve the application subject to conditions being satisfied
- not approve the application
- defer consideration of the application subject to further information being sought and obtained from the investigators or from experts external to the Committee and/or the University of Strathclyde
- take such other decision as is appropriate.

5.2 Applications not approved

Where the application is not approved this decision, and the reasons for reaching that decision, will be communicated to the Chief Investigator in writing. The Committee may give guidance as to modifications that the applicant may wish to consider with a view to making a new application.

5.3 Applications deferred or approved subject to conditions being satisfied

If further information or amendments are sought for a particular application from the relevant investigators, the Convener (or Vice Convener of the Committee) may be delegated authority by the committee to consider the additional information or changes made and either to approve it on behalf of the committee or to return it to the committee for further consideration. The information and amendments must be provided before ethical approval can be given. Any decisions will be reported to the next meeting of the Committee for endorsement.

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6. Amendments to investigations following ethical approval

Once an application is approved the investigators must not deviate from it as approved. The CI must notify the committee of any proposed amendments and allow the committee (or the Convener or Vice Convener on behalf of the committee) time to consider and approve them before implementing them. Similarly, if there is any change to the personnel involved in the investigation, the committee should be asked to approve this amendment and should be provided with details of the qualifications and experience of the new investigator(s). If such amendments are minor they may be handled by the UEC outwith its committee meetings (normally by the Convener or Vice Convener). If, however, the proposed changes are more substantial then they will be considered by the committee at its next meeting and, in some instances, a revised application may be requested. Failure to obtain ethical approval for amendments may invalidate insurance cover.

In the case of an investigation that is the subject of NHS Research Ethics Committee (REC) approval, a copy of the 'substantial amendment form' as obtained from the NHS REC, should be submitted to the UEC for consideration also.

7. Student investigations and investigations of members of staff undertaking degrees

For student investigations involving the NHS please refer to Section 9 below.

It is recognised that many student investigations and dissertations may fall within the remit of this code of practice. Courses, particularly within the social sciences and business subject areas, typically contain large numbers of students who may have made their own project proposals which are usually low risk from the ethical point of view. The responsible academic usually plays a purely supervisory role rather than an investigatory role, although for the purposes of this Code of Practice he or she is formally Chief Investigator (apart from some investigations involving the NHS – see Section 9). In these situations it is valuable for departments to have good screening processes in place to filter out unsuitable investigations before students have invested much time. The scrutiny of those which are to go ahead despite being more complex is prioritised, and a light touch procedure may be used for the other investigations. If this is the case then the generic framework should include a description of these procedures.

Students acting as investigators, and members of staff carrying out research as part of work towards obtaining a degree, should be under the supervision of a member of staff who is minimum Grade 7 (or equivalent). Students, and members of staff in this position, cannot apply for ethical approval themselves (apart from some investigations involving the NHS, see Section 9). Applications must be made by the supervisor acting, for this purpose, as Chief Investigator. The supervisor, on behalf of the University, is responsible for all actions of the students (and members of staff in this position) relating to the investigation and hence it is the supervisor's responsibility to ensure that the student is aware of and observes the relevant guidelines and receives appropriate training in any procedures and techniques to be undertaken as part of the investigation. As with all investigations involving human participants, supervisors should take responsibility for submitting details of the proposed investigations for approval where necessary and for ensuring that all necessary approvals are in place before the investigation commences. See also Section B3 (above) on generic approval.

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8. Collaborative investigations with other universities, non-governmental organisations (NGOs) and other organisations

For investigations involving collaboration with other universities, NGOs or other organisations, applications should be submitted to RKES for consideration of risk management/sponsorship and insurance cover before the investigation begins. Ethical approval is normally only required from the Ethics Committee at one of the collaborating universities or organisations, normally the university or organisation which is sponsoring the investigation. RKES will advise on whether or not the application should be submitted to the UEC at Strathclyde. The University will consider collaborative research with other organisations, providing their ethical processes have been considered by the UEC at Strathclyde to be robust and rigorous. Whatever the ethical approval route, the application will be forwarded by RKES to the Finance Office for confirmation of insurance cover.

9. Investigations involving the NHS, including clinical trials

The UEC Secretariat in RKES can offer advice on sponsorship approval and how to complete the IRAS form and to submit an application to the NHS, and should be contacted early in the procedure. NHS applications cannot be submitted without sponsorship approval so researchers should factor in time for this process when considering submissions.

Ethical approval is required from the NHS for most but not all investigations in which it is involved. Details of the circumstances in which NHS ethical approval is required, and information on the application procedure, can be found on the Integrated Research Application System (IRAS) website at www.myresearchproject.org.uk. Investigations involving NHS staff or undertaken on NHS premises do not necessarily require NHS ethical approval. Please check with the UEC secretariat if you are in doubt. The authority to award ethical approval is delegated to a local NHS Research Ethics Committee (REC), usually in the area where the Chief Investigator and/or the NHS body involved are based. The researcher is not required to submit a University ethics application form as well as an IRAS form, the IRAS form is sufficient. Once NHS approval is in place, then the Convenor will usually endorse the application on behalf of the UEC.

The regulations governing NHS ethical approval are set out in the Governance Arrangements for Research Ethics Committees in Scotland and regulations for research governance in the Research Governance Framework for Health and Community Care (2006).

Research and investigations involving medicines are regulated under the Medicines for Human Use (Clinical Trials) Regulations 2004. All clinical trials must be notified to the Medicines and Healthcare Products Regulatory Agency (MHRA) which approves and licences the use of such products for clinical trials. Similarly, research involving medicinal devices is also regulated by MHRA.

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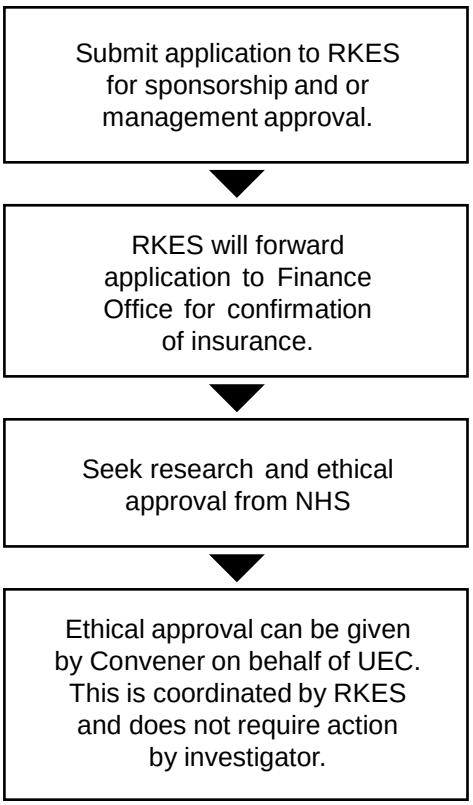
9.1 Process

The application should first be submitted to RKES for sponsorship and management risk approval and confirmation of insurance cover. Approval should then be sought from the NHS, in terms of research and ethical approval. Thereafter, ethical approval can be given by the Convener on behalf of the UEC.



9.2 Honorary contracts

Where a University employee or student, as part of an investigation, is conducting activities which will have a direct impact on the care of NHS patients, the employee or student will be accountable to the NHS body for this work and will need to hold an Honorary contract with the NHS body. The Chief Investigator of such an investigation must ensure that such contracts are in place before work on the investigation proceeds. The Chief Investigator should discuss such contracts with RKES.

9.3 Model agreement for non-commercial research with the NHS

A model agreement for research carried out between Universities and the NHS has been produced by the UK Clinical Research Collaboration (UKCRC). Full details can be found at www.ukcrc.org/regulationgovernance/modelagreements/mnca.aspx.

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The model agreement is a template for documenting the relationship between, and the responsibilities of, the non-commercial sponsor(s) of a research study (the University) and the Health Service organisation where the study takes place. The agreement is intended to be used in a range of research scenarios including clinical trials, medical device studies, research using patient data only, and research using human tissue.

RKES will provide guidance on when this agreement should be used and the implications involved.

9.4 Student investigations

In April 2008, new guidance was issued by the NHS advising that for all doctoral research, the student should be named as Chief Investigator on NHS ethics applications. Full guidance can be found at www.nres.npsa.nhs.uk/applications/faq/before-applying. For research projects below doctoral level, the named CI should normally be the academic supervisor. Please note, although for doctoral research the student should be named as the CI, the responsibilities set out in the Research Governance Framework for Health and Social Care still fall to the academic supervisor in line with Section 7 above.

10. Investigations conducted on other premises

If University staff or students wish to carry out investigations with human participants on premises other than those of the University of Strathclyde they must determine if ethical approval from any collaborating organisation is required (which may be in addition to any ethical approval from the University). Investigators should ensure that this ethical approval is obtained, in order to comply with the University's insurance policies. This is particularly important for investigations where the University is the sponsor. Under such circumstances investigators will also need to comply with the rules and regulations of the collaborating organisation, including health and safety.

11. Any investigations conducted outside the UK, including clinical trials

If University staff or students wish to carry out investigations outside the UK and Europe, then the researcher should clearly identify a local supervisor who can monitor their research. The researcher must ensure that a Code of Practice is sent to the local supervisor.

12. Adverse events

12.1 Adverse events in any type of investigation

If participants report any problems during the course of the investigation (either to the investigator or to the secretary of the UEC) or if the investigators have any cause for concern, the investigation may need to be stopped and the Chief Investigator must inform the UEC of what has occurred. The Chief Investigator must report any untoward event arising during an investigation to the UEC as soon as possible and, where appropriate, to the participant's own doctor with his or her consent. Should such a situation occur then the investigation should be stopped for the individual in question and consideration should be given to stopping the investigation as a whole, depending on the nature and/or severity of the symptom or event. The Secretariat to the UEC will inform the University's Finance Office Insurance Adviser as soon as possible.

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12.2. Adverse events in clinical and other medical/biological trials

For clinical trials the sponsor is required under law to report all serious adverse events and all suspected unexpected adverse reactions that occur to the Medicines and Healthcare Products Regulatory Agency (MHRA). For suspected unexpected serious adverse reactions (SUSARs) which occur in clinical trials where the University is the sponsor these must be reported to the UEC which is required to report to the MHRA within specific time limits. For fatal and life threatening SUSARs the period is seven days for the initial report and a further eight days for additional relevant information. For all other SUSARs the period is 15 days. For clinical trials where the University is not the sponsor, the timescales will be the same but investigators must be aware of the need to follow correct reporting procedures. Sponsors are required, under law, to provide an annual list of all suspected serious adverse reactions in relation to each product being tested.

In addition, where no-fault insurance cover for the investigation has been arranged under the University's clinical trials policy, any serious adverse event must also be reported to the University's Insurance Adviser in the Finance Office as soon as possible, in order that it can be notified to the Insurers as a potential claim.

Participants should also be encouraged to note any unusual or unexpected events or symptoms arising during or after an investigation and report them to the investigator and to their own doctor. Depending on the nature and/or severity of these events or symptoms, the Chief Investigator should report these to the UEC as they might affect the UEC's decisions on any future similar investigation. If a participant does drop out of an investigation, for whatever reason, then the investigators should take reasonable steps to find out whether any harm has come to the individual as a result of participating in the investigation.

13. Related approval procedures

As well as ethical approval, insurance and sponsorship must be in place before an investigation can begin. The procedures are streamlined so that applicants need submit investigations for consideration for ethical, sponsorship and insurance purposes only once, as described above. Section C and Annex 4 provide further guidance on sponsorship and insurance respectively.

SECTION C: Management Approval/ Sponsorship Procedures

1. Introduction

In terms of the University's sponsorship and management risk procedure, all investigations requiring ethical approval must have an identified sponsor. The sponsor is not necessarily the funding body but the individual, or organisation (or group of individuals or organisations) that takes on the ultimate responsibility for confirming there are proper arrangements to initiate, manage, and monitor an investigation. Annex 2 of this Code of Practice sets out the responsibilities of the sponsor.

Normally the sponsor will be the organisation taking the lead for particular aspects of the arrangements for the investigation. In the majority of cases this will be the University. However, where the NHS is involved in an investigation it may take on the role of sponsor solely or jointly with the University (see Section 3 below for more information).

2. Procedures for University sponsorship

Two separate procedures exist for applying to obtain University sponsorship. Depending on the circumstances, an investigation seeking University sponsorship will go through either the RKES procedure or the Head of Department procedure.

2.1. The RKES procedure

Any new investigation involving human subjects which:-

- is within the remit of the UEC (see section B1.1 and 1.2 of the Code of Practice); or
- involves the NHS; or
- has external funding;

must follow the RKES procedure. Only one of the conditions above has to be present for the RKES procedure to apply.

Upon receipt of an ethics application form, the UEC Secretariat in RKES will assess the investigation for sponsorship and risk management and will confirm University sponsorship on behalf of the University unless there are concerns related to sponsorship and/or management risk. If there are concerns (i.e. the human investigation is categorised as medium/high risk in terms of risk) RKES will discuss same with the Senior Officer with responsibility for the UEC. A decision will then be made by RKES and the Senior Officer.

2.2. The Head of Department procedure

Where an investigation:-

- is not within the remit of the UEC; and
- does not involve the NHS; and
- does not have external funding;

the appropriate ethics application form should be submitted by the Chief Investigator to his/her Head of Department. Where the Chief Investigator is the Head of Department the form should be submitted to the appropriate Dean or Deputy Head of Department.

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The Head of Department should consider whether the University is an appropriate sponsor for the investigation and the management risk issues, if any, arising from the investigation. If the Head of Department decides the University is an appropriate sponsor and the project poses low/no management risk issues, the sponsorship section of the UEC form should be signed and dated by the Head of Department.

If the Head of Department is any doubt about the implications of sponsorship or the assessment of management risk issues s/he should contact RKES.

No investigation involving human subjects should begin until sponsorship and ethical approval have been confirmed.

3. Investigations where the University is not being asked to be the sponsor

If the University is not being asked to sponsor the investigation but there are management risk issues associated with the investigation, the paperwork will be reviewed by RKES. A decision as to whether the management risk issues are acceptable to the University will be made.

For investigations that involve the NHS an IRAS form must be completed and submitted online. An investigation submitted through IRAS will be considered by the appropriate ethics committee and also by the appropriate NHS Research & Development (R&D) Office. The R&D office will consider the sponsorship and risk management issues associated with the investigation even if the University or some other organisation is sponsoring the investigation.

4. Insurance

Annex 4 provides useful guidance on insurance issues associated with investigations involving human subjects both from a University and an NHS perspective.

Applications to DECs/SECs automatically have insurance cover from the University.

SECTION D: Record Keeping, Monitoring and Reporting

1. Data protection

The Data Protection Act 1998 concerns the processing of personal data. 'Personal data' is any data which relates to a living individual who can be identified from that data or from that data and other information which is in the possession of, or is likely to come into the possession of, the data controller. 'Sensitive personal data' is information that relates to race/ethnic origin, political opinions, religious beliefs, trade union membership, health (mental or physical) or details of criminal offences. Under the legislation this category of information must be handled with a higher degree of protection at all times. 'Processing' covers anything you do with personal data from collection or receipt right through to disposal or destruction and all the stages in between e.g. copying, release, storage etc.

1.1 Use of personal data in research

It is recognised that some research requires the processing and/or storage of personal and/or sensitive personal data relating to living individuals. The use of any personal data is governed by the Data Protection Act 1998 (DPA). If your research involves the processing of personal data you must comply with the Act and the University's current Data Protection Policy. The University's policy and supporting guidance for staff is available from www.strath.ac.uk/dataprotection.

It should be noted that the University's Data Protection Policy and guidance are there to assist staff. However, they will not provide in-depth detail regarding every eventuality relating to data protection in research projects. Therefore, if you are unsure about any aspect regarding data protection you should discuss this with the Chief Investigator or the Information Governance Unit (dataprotection@strath.ac.uk). You should consider the data protection implications at the outset of your research project and build appropriate processes/safeguards into the project as required. Please note that if you fully anonymise data so that no living individual can be identified from it/related to it then it is no longer considered 'personal data' under the Act and there will be no data protection implications.

1.2 Data protection principles

The University must comply with the eight data protection principles as set out in the Act. In summary these state that personal data shall:

- be obtained and processed fairly and lawfully and shall not be processed unless certain conditions are met,
- be obtained for a specified and lawful purpose and shall not be processed in any manner incompatible with that purpose,
- be adequate, relevant and not excessive for that purpose,
- be accurate and kept up to date,
- not be kept for longer than is necessary for that purpose,
- be processed in accordance with the data subject's rights,
- be kept safe from unauthorised access, accidental loss or destruction, and
- not be transferred to a country outside the European Economic Area, unless that country has equivalent levels of protection for personal data.

In order to ensure that you comply with these principles you should have a clear plan for how you will process personal data i.e. how will you gather, use, store, retain and destroy this information?

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1.3 Research data exemption

Under Section 33 of the Data Protection Act 1998 personal data may be exempt from some of the data protection principles as long as the research activity fulfils certain conditions. To be exempt from some of the data protection principles the research activity must fulfil all of the following conditions:

- The personal data is being used exclusively for research purposes (includes statistical or historical research purposes). The personal data must have no other use, not even incidental use;
- The personal data is not being used to support measures or decisions relating to any identifiable living individual (not just the data subject but anyone who may be affected by your research);
- The personal data is not being used in a way that will cause, or is likely to cause, substantial damage or substantial distress to any data subject; and
- The results of the research activity, or any resulting statistics, must not be available in a form that identifies the data subjects.

If the research activity cannot fulfil all of the conditions set out above then the exemption cannot apply.

If the research activity does fulfil the conditions set out above then the personal data may be used in the following ways:

1.3.1 May be used for a new purpose

Under the second data protection principle, personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or purposes. However, if the research activity fulfils the conditions above then the second part of this principle does not apply. The personal data can then be processed for another purpose.

1.3.2 May keep the personal data for a research purpose

The fifth data protection principle says that personal data processed for any purpose or purposes shall not be kept for longer than is necessary for that purpose or purposes.

However, if the research activity fulfils the conditions above then this does not apply and personal data can be retained for longer than is necessary for that purpose. If required the data can be retained indefinitely.

1.3.4 Need not provide personal data under the subject right of access.

The sixth data protection principle requires that personal data shall be processed in accordance with the rights of data subjects set out in Section 7 of the Act.

One of the rights of individuals is the right of access to their own personal data. Personal data that forms part of a programme of research may be exempt from this right provided that the research activity has met all the conditions for the Research Exemption.

This only applies if:

- The personal data is processed in compliance with the relevant conditions.
- The results of research or resulting statistics are not made available in a form which identifies data subjects.

However, it should be noted that it still good practice to inform participants at the outset if there is an intention to use their personal data again and how long it will be held for (if this is known at the time). If it is clear that personal data will never be of any further use then it is appropriate to destroy it after a set period of time.

SECTION D: Record Keeping, Monitoring and Reporting

If participants were specifically told that data would be destroyed after a certain period of time then this should be adhered to unless it is possible to go back to the participants and ask for their permission to retain the data for longer.

2. Data management and record-keeping

It is essential that all University records are managed appropriately, including those related to research. Records may be held in many formats i.e. databases, hard copy, Microsoft Office documents etc. The theories of good data and records management apply irrespective of the format or medium in which that information is held. You should consider the format/medium when planning how you will handle data. Please note that the Information Governance Unit has created a number of records management guidance notes to assist staff with managing records (www.strath.ac.uk/is/compliance/recordsmanagement/#d.en.611686).

2.1 Data planning

It is good practice to create a data plan at the outset of any research project, whether externally-funded or not. It is likely that data planning will be built into the funding application process. Most funders provide policies and guidance on managing your data, which should be available to you via the funder's website, or by contacting the funder directly. The basic points that a data plan should address are data management, access and preservation.

For projects that include personal and/or sensitive personal data it is even more important to consider how these datasets will be managed at the outset of the project. These arrangements may be reviewed during the research or upon completion.

2.2 Data management responsibilities

The CI is responsible for ensuring that all data, including any personal data, gathered in the course of a programme of research is managed appropriately. The CI should ensure that he/she is aware of the University's Data Protection Policy and any relevant guidance for staff that may be relevant in relation to his/her research and the management of data (www.strath.ac.uk/dataprotection/dppoliciesandguidance).

2.3 Data security

It is essential that all data is managed with appropriate security. This is true irrespective of the media on which the data is stored i.e. hard copy or electronic. In the case of personal data the seventh data protection principle states that personal data shall be kept safe from unauthorised access, accidental loss or destruction.

Keeping data secure involves both operational and technical measures. All staff involved in research projects should be aware of any project-specific measures, as well as University policies and procedures in relation to data/IT security.

As a minimum staff should be aware of the following:

- Access to information should be suitably secure and restricted to only staff who require access e.g. hard copy records should be held securely in lockable cabinets, electronic records should be on secure drives.
- Electronic data should never be stored on desktops or C drives. These are not backed up to the University network and are therefore considered insecure.

SECTION D: Record Keeping, Monitoring and Reporting

- The use of portable electronic storage devices should be avoided, unless absolutely necessary. The possibility of remotely accessing data held on secure University servers should be considered. If you must take data off-site consider if you can render any personal data anonymous first. This means ensuring that no individual can be identified from that data.
- If portable devices must be used for confidential information and/or personal data then they must be encrypted. This is considered by the Information Commissioner (who enforces Data Protection) to be the minimum level of security which should to be applied to personal data held on portable media.

Information Services should be contacted for additional information regarding encryption and other security measures related to electronic data. The University's encryption policy should be followed by all researchers (www.strath.ac.uk/it/security/encryption).

Records Management Guidance notes produced by the Information Governance Unit are available on this topic, including:

- information security
- determining if information is confidential
- storing records.

2.4 Sharing data

If you are working on a project in collaboration with another institution/organisation then you should ensure that a suitable agreement is in place regarding data sharing. This is of particular concern where personal data is involved. A suitable agreement should be in place which will outline the roles and responsibilities of both sides. This may also address potential issues in relation to Intellectual Property Rights. In addition, where personal data is involved, an appropriate agreement will include a data sharing agreement which will clearly define the roles of data controller and data processor. Advice should be sought from RKES.

2.5 Retention of data

As stated above, it is good practice to inform participants how long their personal data will be retained at the outset, if know. Many funding councils will set periods for which research data must be retained. These will usually be stipulated at the outset. You must ensure that you have a plan as to how and where data where will be stored and how long for. In the case of clinical trials or investigations involving the NHS where the University is acting as sponsor or co-sponsor, or where no-fault insurance cover has been arranged, arrangements must be made for long-term retention of all relevant information. This will include retaining a copy of the original application (together with any approved amendments), copies of the signed consent form for each individual who participated in the investigation, copies of the signed conditions of compensation forms for each participant where appropriate (see Annex 4 on Insurance) and any other relevant documentation.

The fifth data protection principle states that personal data should not be retained for longer than is necessary (in relation to the purpose for which it was collected). Again, there may be requirements by funders in relation to how long any personal data must be retained. You should check with the relevant funding body.

If no external funding requirements are involved then you should consider how long data must be retained for legal, statutory or organisational requirements.

N.B. Personal data does not need to be retained in line with the fifth data protection principle if it meets the criteria of the research exemption under S33 of the Act. See Section 1.3 Research Data Exemption above for more information.

SECTION D: Record Keeping, Monitoring and Reporting

2.6 Disposal of data

When data no longer requires to be kept then you must dispose of it appropriately. Confidential waste, including any personal data, must be disposed of securely. This may require:

- confidential shredding of hard copy material
- permanent deletion of electronic data
- suitable disposal of IT storage devices i.e. CD Roms/hard drives etc.

Information Services can provide more information related to removing or deleting electronic data. Estates Services can provide more information on recycling and waste management (www.strath.ac.uk/estates/recycling)

2.7 University Ethics Committee records

All records relating to the ethics committee are maintained by the relevant department (at the time of writing this is RKES). These records will be retained for an appropriate time as required by the University to meet its statutory, regulatory or administrative requirements.

2.8 Departmental Ethics Committee records and monitoring

DECs are required to report to the UEC on an annual basis. This report will include information on all investigations that the DEC has considered throughout the year, including student investigations, together with information on whether or not the investigations were approved. DECs should also keep records of meetings, decisions, amendments to applications and investigations, and copies of correspondence relating to all applications that are considered.

3. Monitoring

3.1 Monitoring of investigations approved by the University Ethics Committee

The UEC will monitor all proposals submitted for ethical approval. This will normally be conducted on an annual basis using the UEC Monitoring Report Form.

At the conclusion of the investigation for which ethical approval has been granted, the CI will report back to the UEC on the outcome of the investigation with an account of anything which may have occurred within the investigation that may prompt ethical questions for any similar future investigation and with anything else that they feel the UEC should know.

SECTION D: Record Keeping, Monitoring and Reporting

3.2 Monitoring of generic framework Investigations

The DEC/SEC will be responsible for monitoring all the work undertaken as part of any generic framework, approved by either the UEC or the DEC/SEC, and will report back to the UEC in its annual monitoring report (see above). This report will either confirm that all work undertaken falls within the parameters of the generic framework as approved, or will indicate where any changes have been made. It will also identify if any unexpected events occurred during the study.

SECTION E: ANNEXES

1. Glossary
2. Key responsibilities of the Sponsor
3. Key responsibilities of the Chief Investigator
4. Insurance
5. Note on the law governing research involving human tissue
6. Research in relation to deceased persons
7. Definition of medical devices

SECTION E: ANNEXES

ANNEX 1 GLOSSARY

Adverse event – any problems that might arise during an investigation. The Chief Investigator must report any untoward event to the ethics committee and the investigation may have to be stopped. Further information is contained in Section B12.

Consent – when participants agree to take part in the investigation. This is explained in more detail in Section B4 under 4.3.8.

Chief Investigator – the lead investigator who has overall responsibility for the investigation. A full description of the role and responsibilities of the Chief Investigator is given in Annex 3.

Clinical trial – the University has adopted the definition used by the Medicines for Human Use (Clinical Trials) Regulations 2004 which define a clinical trial as 'any investigation in human subjects, other than a non-interventional trial, intended:

a. to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products,
b. to identify any adverse reactions to one or more such products, or
c. to study absorption, distribution, metabolism and excretion of one or more such products, with the object of ascertaining the safety or efficacy of those products.'

In order to assist investigators determine whether or not their investigation is a clinical trial the MHRA has produced an algorithm – this is available at the following web site:
www.mhra.gov.uk/home/idcplg?IdcService=SS_GET_PAGE&nodeId=723

Separate insurance arrangements may need to be put in place for clinical trials – further information is contained in Annex 5.

Generic approval – approval for a number of investigations that fall within an agreed framework (e.g. student projects), or approval to run an investigation using the same procedures on a number of occasions. A full description of generic approval is given in Section B3.

Investigation – a study to explore particular conditions, behaviours, opinions or reactions to particular stimuli, in order to gain more information

IRAS - Integrated Research Application System (replaces NRES online application form).

MHRA – Medicines and Healthcare Products Regulatory Agency
Monitoring –the UEC and the DEC/SECs will undertake regular monitoring of all the protocols that they approve, to ensure that the protocol has been adhered to and to identify any issues that might have arisen. Additionally the UEC will seek an annual report from the DEC/SEC's on their activities.

Participant - a person is considered to be a participant in an investigation if they are contributing data into that investigation either actively (for example through taking part in a survey or undertaking particular tasks) or passively (for example through being the subject of observation).

Principal Investigator – where an investigation is conducted on more than one site a Principal Investigator will be identified for each site. The Principal Investigator will be the lead researcher at that site.

Protocol – a description of the investigation to be undertaken including the investigators involved, where the investigation will take place and under what conditions, the methods and procedures to be used, the number of participants being sought, the inclusion/exclusion criteria to be applied, and the likely duration of the investigation.

SECTION E: ANNEXES

Sponsor – the individual, institution, company or organisation that takes responsibility for securing the arrangements to initiate, manage and finance the investigation, including ensuring that all necessary approvals are in place. A full description of the role and responsibilities of the sponsor is given in Annex 3.

SUSAR – suspected unexpected serious adverse reaction. Where a SUSAR occurs in any clinical trial where the University is the sponsor these must be reported to the ethics committee which is required to report to the MHRA within specified time limits. For clinical trials where the University is not the sponsor the timescales will be the same but investigators must follow the correct reporting procedures. Sponsors are required under law to provide an annual list of all suspected SUSAR's in relation to each product being tested. Further information is available at Section B12.

SECTION E: ANNEXES

ANNEX 2 KEY RESPONSIBILITIES OF THE SPONSOR

The sponsor is the individual, institution, company or organisation that takes on the ultimate responsibility for the initiation and management (or arranging the initiation or management) of, and the financing (or arranging the financing) for, the investigation. The sponsor is responsible for all aspects of the investigation and for seeking all appropriate approvals, ensuring that the research protocol has passed scientific/peer quality assurance, and ensuring that arrangements are in place for good practice in conducting the investigation, for monitoring the progress of the investigation and for reporting the outcomes. The key responsibilities of the sponsor are:

- The research proposal respects the dignity, rights, safety and well-being of participants and the relationship with care professionals;
- An appropriate process of independent expert review has demonstrated that the research proposal is worthwhile, of high scientific quality and good value for money;
- An appropriate ethics committee has given a favourable opinion;
- In the case of a clinical trial involving a medicine, someone acting on behalf of the sponsor obtains a clinical trial authorisation and the arrangements for the trial comply with the law;
- Appropriate arrangements are in place for the registration of a trial;
- The chief investigator, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully;
- The arrangements and resources proposed will allow the collection of high quality, accurate data and the systems and resources proposed are those required to allow appropriate data analysis and data protection;
- Arrangements proposed for the work are consistent with this research governance framework;
- Organisations and individuals involved in the research agree the division of responsibilities between them;
- There is written agreement about the arrangements for the management and monitoring of the study;
- Arrangements are in place for the sponsor and other stakeholder organisations to be alerted if significant developments occur as the study progresses, whether in relation to the safety of individuals or to scientific direction;
- Agreement has been reached about compensation in the event of harm to research participants and if any organisation, or the sponsor itself, offers compensation without proof of negligence, it has made the necessary financial arrangements;
- There are arrangements for the conclusion of the study including appropriate plans for disseminating the findings;
- Scientific judgements made by the sponsor in relation to these responsibilities should be based on independent and expert advice;
- The sponsor is expected to assist any enquiry, audit or investigation related to the funded work.

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ANNEX 3 KEY RESPONSIBILITIES OF THE CHIEF INVESTIGATOR

The Chief Investigator is the lead investigator for the investigation and is responsible for the following:

- The research team gives priority at all times to the dignity, rights, safety and well-being of participants;
- The study complies with all legal and ethical requirements;
- The research is carried out to the standards in this research governance framework;
- Controlled trials are registered and for clinical trials involving medicines, the research follows any conditions imposed by the licensing authority;
- The Chief Executive of the organisation(s) involved and/or any other individual(s) with responsibilities within this framework are informed that the study is planned, and their permission is obtained before the research starts;
- When a study involves participants under the care of a doctor, nurse or other worker for the condition to which the study relates, those care professionals are informed that their patients or users are being invited to participate and agree to retain overall responsibility for their care;
- When the research involves a service user or carer or a child, looked after or receiving services under the auspices of the local authority, the agency director or their deputy or other appropriate person (e.g. social worker) agrees to the person (and/or their carer) being invited to participate and is fully aware of the arrangements for dealing with any disclosures or other relevant information;
- Potential participants and other service users and carers are involved in the design and management of the study whenever appropriate;
- The study is submitted for ethics review and it does not start without a favourable opinion, and the research team acts on any conditions attached to the ethics opinion;
- Unless participants or the ethics opinion says otherwise, participants' care professionals are given any information directly relevant to their care that arises in the research;
- Each member of the research team, including those at collaborating sites, is qualified by education, training and experience to discharge his/her role in the study and their qualifications are documented;
- Each investigator in a clinical trial involving medicines is aware of his/her legal duties;
- Students and new researchers have adequate supervision, support and training;
- Unless urgent safety measures are necessary, the research follows the protocol or proposal agreed by the relevant ethics committee and by the sponsor;
- Substantive changes to the protocol or proposal are submitted for ethical review and for the sponsor's agreement. These amendments are implemented only when approved;
- Procedures are kept in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage;
- Arrangements are made for the appropriate archiving of data when the research has finished and to make it accessible;
- Reports on the progress and outcomes of the work required by the sponsor, funders, or others with a legitimate interest are produced on time and to an acceptable standard;
- The findings from the work are opened to critical review through the accepted scientific and professional channels;
- Once established, findings from the work are disseminated promptly and fed back as appropriate to participants;
- The chief investigator accepts a key role in detecting and preventing scientific misconduct by adopting the role of guarantor on published outputs;
- Arrangements are kept in place for the management of financial and other resources provided for the study, including for the management of any intellectual property arising;
- All data and documentation associated with the study are available at the request of the inspection and auditing authorities.

Please note:

- Ensuring that final revisions have been communicated to UEC within one year of initial review by UEC of the application for ethical approval. Failure to do so will mean that a new application must be submitted.
- If an investigator leaves the University then agreement must be reached on who is responsible for the files, notes and records relating to the investigation - normally this is the sponsor.

SECTION E: ANNEXES

ANNEX 4 INSURANCE

1. Outline of Insurance Policies

The University maintains a range of insurance policies including -

- Employer's Liability - which indemnifies the University against its liability for accidental injury to its employees suffered during the course of their duties
- Public Liability - which indemnifies the University against its liability for accidental injury to persons and for accidental damage to the property of others
- Products Liability
- Professional Indemnity
- Clinical Trials - under which no-fault cover is available.

Applications to the UEC should be accompanied by a completed insurance questionnaire. The information provided in the insurance cover questionnaire will allow UEC to either confirm insurance cover or refer the application to Finance for further checks. In cases where ethical approval is required from a collaborating university or the NHS, but not the University, confirmation of insurance cover will also be sought. It must be made clear at the time of submission if the University is acting as Sponsor or Co-Sponsor for the research proposed. Ethical and management approval is only given when appropriate insurance cover is in place.

The purpose of the University's insurance policies is to indemnify the University of Strathclyde (including its staff, students, and ethics committee members, while working under the control of the University and on University business), and not external investigators/organisations.

2. Liability vs no fault insurance

The University holds two types of insurance to cover claims arising as a result of its involvement in research involving human subjects / clinical trials:

2.1 Legal liability cover

Legal liability cover is available under but the Public Liability policy and the Clinical Trials policy.

Legal liability policies provide cover for loss/harm to individuals resulting from their participation in a research study or clinical trial where the University has been proven to be legally liable for that loss/harm. These policies place a burden of proof upon the claimant to prove the University's liability for their loss.

2.2 No fault cover

No fault cover is provided by the University's Clinical Trials Policy.

No fault insurance is intended to provide compensation to clinical trial research subjects in the event of their suffering a significant harm/loss which, on balance of probabilities, is directly attributable to their involvement in the trial. There is no requirement for the claimant to prove negligence on the part of the University.

For example, a research subject may experience an unexpected adverse reaction which was not caused by negligence. Under a legal liability policy no cover would apply but a no fault policy will provide compensation in this instance.

The insurance cover appropriate for most University investigations will be Legal Liability cover.

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3. Conditions of cover and exclusions

Insurance cover may be invalidated if the conditions of cover are not complied with:

- Studies must not commence until ethical approval (as required by this Code or by other legislation/ guidelines) has been obtained or, where ethical approval is required for a proposed amendment, until approval of the amendment is obtained.
- All material facts must be disclosed to insurers.
- The University must take reasonable precautions to prevent any event which may give rise to a claim.
- All legislation, regulations and guidelines (including this Code and the decisions of University ethics committees) relevant to a particular investigation should be followed.
- Insurers must be notified of claims, *or of circumstances which have the potential to lead to a claim*, as soon as possible. A delay in notification could result in the absence of cover.

Not all legal liabilities are covered by the University's policies. Exclusions under the Public Liability policy include:

- liability arising from use of aircraft/aerial/aeorspatial devices
- liability arising from water borne craft
- liability arising from ionising radiation/nuclear components
- fines and penalties
- legal liabilities assumed by the University under contract/agreement which would not otherwise have attached.

Exclusions under the Clinical Trials policy include, but are not limited to:

- clinical trials outside the UK
- research subjects known to be pregnant at the time of the trial
- research subjects under 5 years of age
- trials with the purpose of assisting with or altering the process of conception
- investigating or participation in methods of contraception
- trials involving genetic engineering (other than a Clinical Trial in which Medicinal Purpose is treating, preventing and diagnosing disease)
- trials where the substance under investigation has been designed, altered or manufactured by the University
- fines and penalties
- legal liabilities assumed by the University under contract/agreement which would not otherwise have attached.

Where an activity is normally excluded it *may* be possible to arrange an extension to the policy on provision of additional information and/or an additional premium.

All investigations taking place overseas must be referred to UEC for confirmation of insurance cover.

Many contracts may require that the University waive rights of recovery and/or hold harmless the other party to the agreement. It should be noted that if this is done without the express approval of insurers, the policies claims conditions will have been breached and insurers may avoid the claim. Such agreements must therefore be referred to the University's Insurance Adviser prior to the commencement of the investigation.

Further details on policy conditions and exclusions can be obtained from the University's Insurance Adviser as required.

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4. Clinical trials insurance cover

The University holds a Clinical Trials policy (limit of indemnity £30M any one event and in the aggregate) which provides cover for losses arising from Clinical Trials except those specifically excluded.

Insurers define a Clinical Trial as “an investigation or a series of investigations conducted on any person for a Medicinal Purpose” where Medicinal Purpose is defined as:

- treating or preventing disease
- diagnosing disease or ascertaining the existence, degree of, or extent of, a physiological condition
- assisting with, or altering in any way, the process of conception or investigating or participating in methods of conception or contraception
- inducing anaesthesia
- otherwise preventing or interfering with the normal operation of a physiological function.

The policy has a number of policy conditions and exclusions as outlined in Section 3 on Conditions of Cover and Exclusions.

The Clinical Trials policy provides both legal liability and no fault cover. In most instances legal liability cover will be the most appropriate cover for University activities. The decision whether or not to offer No Fault cover for a particular investigation rests with the UEC. Investigators should therefore not state in their applications that no-fault compensation cover is in place if this is not in fact the case.

There is no legal requirement for no-fault compensation to be offered for investigations involving human participants in the UK. Some organisations (e.g. NHS bodies) will not be in a position to offer no-fault compensation.

No Fault cover is most likely to be considered where:

- the investigation is a clinical trial and involves potential harm to participants
- the investigation is a clinical trial and there is potential for damage to the University’s standing.

Depending on the number and nature of investigations for which no-fault cover is requested, additional premium may be due. A claim by participants will only be covered if there is a valid policy at the time of the claim and the claim is notified during the policy period.

5. Claims and potential claims

Any claim for compensation, or specific event which has the potential to give rise to a claim, must be reported to the University’s Insurance Adviser in Finance as soon as possible, in order that it can be notified to the Insurers as a claim/potential claim.

6. Individual members’ liability

In addition to the policies outlined at Section 1 above, the University has in place Directors and Officers Liability cover. This specifically provides cover for all directors and officers of the University and its subsidiaries. This includes all members (staff and lay members) of the UEC and the DEC/SECs. This provides cover for any ‘wrongful act’, i.e. any error, misstatement, act, omission, neglect or breach of duty committed, attempted or allegedly committed or attempted by an insured person acting in this capacity. It will provide for the amount which the insured is legally and personally liable to pay in respect of claims including defence costs, legal representation expenses and awards of damages.

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ANNEX 5 NOTE ON THE LAW GOVERNING RESEARCH INVOLVING HUMAN TISSUE

Human tissue taken from a living person

This note is confined to the law in Scotland, relating to research involving human tissue taken from a living person. It is understood that no research that is likely to come before the Committee is carried out on human tissue taken from dead bodies. (A different set of rules under Human Tissue (Scotland) Act 2006 applies to such research).

Scotland compared with England and Wales.

The law applicable to the question in Scotland is

a. Scots common law as it applies to determine who owns material taken from a living body
b. A small number of the provisions in the Human Tissue Act 2004, essentially for our purpose Section 45 with Schedule 4, which creates a criminal offence if material is taken for DNA analysis in certain circumstances

In England, by contrast, almost all the law is contained in the whole of the Human Tissue Act 2004. That contains *inter alia* elaborate provisions regulating consent.

What counts as material from a living body, research on which is governed by the law in Scotland?

Except for the purpose of the criminal offence relating to material taken for DNA analysis there is no statutory definition applicable to material taken from a living person in Scotland.

It must be assumed that any material generated by and then separated from a living person's body has to be considered. The exception in the English statutory law, excluding "hair and nail" (Human Tissue Act 2004 section 53) does not apply in Scots (common) law. There is also no rule excluding very small quantities in Scotland.

Who owns it?

Probably (see Niall Whitty, SME, sv Medical Law para 340) at the moment it is separated from the body, the person from whose body it has come. Though there is no other authority on the matter in Scots law, I consider that should the question ever required to be determined by a court, it would take this view, following the approach in a number of other jurisdictions.

That person can donate it to another – e.g. to the investigator, the institution employing the investigator and so on. (Some material cannot legally be sold)

The relation of "Donation" to "Consent" to use

Once something is donated the person from whom it comes no longer has a right or interest in what is then done with it. A possible exception may be where something is done that would affect that person's dignity, which is highly unlikely in the context of research.

The question is therefore correctly one of donation rather than consent to use. However, if a person insisted on not donating the material, then the question would arise as to consent to use. In such a situation, which is unlikely, it would be appropriate to follow the guidelines in the English legislation, not as law, but as appropriate ethical rules.

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How is donation achieved?

It is probably implied in the research context. But for the avoidance of doubt it should be specifically stated in the consent form.

Material for DNA analysis – New Statutory Criminal Offence

Section 45 (with Schedule 4) of the Human Tissue Act 2004 makes it a criminal offence in Scotland (as well as in England Wales and Northern Ireland) to have "bodily material" for DNA analysis in certain circumstances. The offence can be committed by the institution as well as an individual (see Section 49).

There are four conditions all of which are required for the offence to be committed (Section 45(1):

- There is "bodily material" (defined as material "from a human body [alive or dead] that "consists of or includes human cells")
- A person [which can be an institution such as a university] has it
- That person intends that DNA in it be analysed and intends that the results of that analysis be used, other than for medical diagnosis or treatment of the person from whom it comes, criminal justice and such things (Schedule 4 Part 2), or for certain sorts of medical research where the person from whom it has come cannot be traced (once Regulations have been made for this; the Court of Session, when that happens/if it happens is the supervisory body in Scotland).
- There is no "consent" (as defined in the legislation) from the person from whom it has come (or from the relevant other party as defined in the legislation where the person is a "child" or has cognitive impairment.

SECTION E: ANNEXES

ANNEX 6 RESEARCH IN RELATION TO DECEASED PERSONS

1. Practical issues

The University of Strathclyde does not have a Medical School or Anatomy Department and does not routinely receive bodies donated for medical research. However the University is licensed under the Anatomy Act through its department of Biomedical Engineering and can examine and store cadaveric tissue at this facility. Alternatively cadaveric samples can be obtained through collaboration with such departments (e.g. the Anatomy Department of Glasgow University) or via importation from an appropriate source. According to the Anatomy Act, only licensed individuals may import tissue, and therefore the only source of tissue for non-licensed departments and individuals is through collaboration.

If you wish to work with cadaveric tissue for the purpose of transplantation studies, then a separate licence must be obtained from the Human Tissue Authority (see www.hta.gov.uk/licensingandinspections/licenceapplicationstep-by-stepguide.cfm).

2. Ethical issues

All research involving cadaveric tissue should be reviewed by the UEC unless devolved to a DEC/SEC. The overwhelming ethical issue regarding the use of cadaveric human tissue concerns consent: whether the intended use is compatible with the written consent given by the donor prior to death; that the tissue is treated respectfully during the research programme and that the tissue is disposed of in accordance with the wishes of the deceased. A secondary ethical issue is one of health and safety of the staff and students performing the research.

Ethics applications must demonstrate that the intended research is appropriate based on the donor consent, and that training associated with the manual handling of the tissue is more than adequate to ensure researcher safety.

3. Research using tissue obtained from living donors

Such tissues are obtained via regulated tissue banks, which have generic NHS (the UK ones do) approval for research purposes. After their committee reviews an application for tissue, and approves it, they release anonymous tissue on that basis. Such research must still gain ethical approval at the University of Strathclyde. However, tissue obtained from a NHS tissue bank will be assumed to have been ethically obtained and researchers should include the letter of approval from tissue banks within their application.

SECTION E: ANNEXES

ANNEX 7 DEFINITION OF MEDICAL DEVICES

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

For the purposes of the Medical Devices Directive, the following definitions shall apply:

A ‘medical device’ means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

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