

GUIDELINES AND PROCEDURES FOR THE ETHICAL CONDUCT OF RESEARCH PROJECTS AND DISSERTATIONS

1. PREAMBLE

It is important that the University and the School are confident that the research carried out under its auspices is done in accordance with 'best practice' and within appropriate international guidelines laid down to protect participants, including the staff and students undertaking the research. (i.e., 'saving the researchers from themselves'). There are a number of codes concerning experimentation on human beings, most of which are based on the Declaration of Helsinki (1964, latest revision 2000). Several professional bodies and associations have also issued guidelines for their members; amongst these are the *British Association of Sport & Exercise Sciences*, the *British Psychological Society*, the *British Sociological Association* and the *Physiological Society*.

In addition, many institutions have formulated local codes of practice to provide more detailed guidance for staff involved in experimentation involving human beings. Local ethics committees have also been established to oversee investigations involving human participants and to consider individual proposals. Indeed, it is now a pre-requisite to application for external funding and publication that such approval is obtained.

The School seeks to ensure that the conduct of all staff and students carrying out work involving human participants, whether physiological, psychological or sociological, conforms to accepted professional standards. The School's Research Ethics Committee is a Sub-Committee of the Research Committee and has been established to guide and assist investigators and to ensure that full consideration is given to the health, safety and well-being of the participants taking part and that the rights of the participants are protected.

Please also refer to the accompanying document on Ethical Principles (ETHICS_principles.doc) and the Helsinki Declaration (Helsinki.doc) that are available on WebCT.

2. GENERAL PRINCIPLES

2.1 Physical health and safety

It is necessary to consider the risks of the procedures and the action to be taken in the case of a mishap. In both cases it is important to bear in mind:

- The type of participants
- The equipment and location of the work
- The number and frequency of procedures
- The competence of the investigators

Please also refer to the section on Health and Safety Issues

2.2 Ethical Issues

The aim of the School's procedures is to ensure that participants do not feel that they have been abused as a result of taking part in a study. The definition of abuse will include unexpected pain or discomfort and embarrassment or humiliation experienced during the course of a procedure. Central to this issue is the question of consent (see also ETHICS_principles.doc on WebCT).

Some of the procedures carried out in the School (particularly in Sports Science) involve a degree of risk, discomfort and potential embarrassment; it is essential that participants are made aware of these factors prior to agreeing to take part. Volunteers should never feel under any compulsion to participate and should be free to withdraw at any stage, without consequences, or the need to provide a reason for withdrawal. The question of consent is particularly sensitive in the case of students, junior, or support staff. It is not normally

desirable for sub-ordinates in close contact with a member of staff acting as investigator to be recruited, as they may feel vulnerable to pressure from someone in a position to influence their careers. On the other hand, it is normally reasonable for students to be recruited to take part in teaching exercises where one of the primary objectives is to enable them to make their own observations. The investigator also has a duty to maintain the confidentiality of the participants' data and should be aware of the requirements of the Data Protection Act (1984).

In reaching a decision about the acceptability of a proposed investigation the Research Ethics Committee of the School will weigh the 'value' of the possible results against the risk and discomforts of participation. The Committee therefore needs to know the methodological background and the justification for the study, together with the following information about the proposed investigation:

2.2.1 The type of participants: It will be necessary to specify the age, sex, state of health and type of participant, e.g. student, members of staff, members of the public etc. and the method of recruitment. Clearly procedures that may be of little concern for one type of participant may be far more contentious for another group. In some cases it may be necessary to screen and select participants. Details will be required of these processes in the light of the risks involved in the investigation.

2.2.2 The methodology: Details of the procedure should include the duration of the experiment and details of any painful or potentially embarrassing events; the latter may be states of undress, collection of body fluids etc.

2.3.3 The circumstances: This section will give information as to whether the procedure is part of a teaching practical or a research project, whether it is likely to be a rare or routine event and whether it will be undertaken alone or together with other procedures.

2.3.4 The location: Some procedures will only be acceptable if carried out in specific locations. This will usually be because of access to suitable first aid or resuscitation equipment or personnel, but it may also be important to consider whether the location has any bearing on questions of embarrassment and sexual harassment.

2.3.5 The investigators: The investigator must be competent to carry out the procedures and consideration must be given to the number of assistants required to ensure safety and, where appropriate, the proper chaperoning of participants.

2.3.6 The risks: It is essential that realistic assessments are made of the likelihood and severity of any injuries arising from the investigation. When advising participants of discomforts and risks it is useful to relate these to activities with which the participants may be familiar e.g. the possibility of injury whilst playing a game of football, crossing a main road etc. Both the physical and psychological risks must be included, and consideration should always be given to the potential embarrassment and distress caused by a questionnaire or interview in which participants are asked about attitudes or behaviour.

2.3.7 The precautions: Having identified the risks, the next stage is to ensure that appropriate steps are taken to minimise the chance of any mishap and that, should a mishap occur, the appropriate staff are on hand and procedures in place to deal with the situation. Consideration should be given not only to first aid but also to longer-term care and rehabilitation of the injured participant.

2.3.8 Informed consent: Full informed consent is the ideal to strive for and in many cases this may involve potential participants experiencing some of the sensations and procedures in a procedure before committing themselves. Whether or not this is feasible, the participant should receive a full explanation about the purpose, procedure, discomforts, risks and precautions entailed in the investigation. For some simple procedures oral explanations and consent may be sufficient but wherever there is appreciable risk or discomfort, written explanations and consent forms are required. In social science research participants should be given as much information about the research as possible in order that they are able to make an informed decision about participation. Consent should be freely given and the

participants must be informed that they are free to withdraw at any time without having to give an explanation. In judging whether consent is freely given it must be born in mind that students, junior staff or patients may feel under an obligation to participate in experiments. Interviewing and selecting participants for demanding investigations may be handled better by a third party who has no other involvement with the participants or the study. The other factor to be considered is payment to participants. Substantial payments will undoubtedly encourage some participants to participate in studies they would not normally countenance. Payments may be made as a compensation for time spent on the project, loss of earnings, for meals and transport or other expenditure, but it must be quite clear that the payments are not intended to induce participants to accept risks or pain that they would not normally tolerate.

3. LEGAL ISSUES (check with University's legal and insurance advisors)

All investigators must be aware of their, and the University's, legal responsibilities. If an injury occurs during an experiment, the investigator and the university could be sued for damages. For this to be successful, the complainant is required to prove negligence. If the proper procedures have been followed, there should be a good defence against a charge of negligence. There is no entitlement to compensation in the absence of proof of negligence.

The contractual position of members of staff is that the University accepts vicarious liability for staff performing their legitimate duties. This does not mean that the University will tolerate malpractice. The University's insurance covers all procedures on human participants, provided the Research Ethics Committee has approved them. It is in everyone's best interests to ensure that all procedures are approved.

Where research is sponsored by an outside organisation it is important to clarify the insurance position. The usual practice is that, for example, a pharmaceutical company accepts full liability for drug trials. Any such contract should be negotiated through Brunel Enterprise Centre (BEC) and approved by the University's Legal Office.

If a study involves volunteers who are **nationals of the USA or Canada**, special dispensation is required.

4. CODE OF CONDUCT

All research investigations undertaken by staff and doctoral students in the School must be approved by the School's Research Ethics Committee.

4.1. Lines of responsibility: It is the responsibility of the Head of School to ensure that staff are competent to use equipment and are familiar with safe working practices. Likewise it is the responsibility for members of staff to ensure that those working under their supervision, including collaborators, are competent and follow these guidelines.

4.2. Recruitment: The recruitment of participants should, wherever possible, be via a notice, or if verbally, through a group approach rather than to individuals. Where there are complex issues to be explained, a third party may be involved (see Section 2.2.8)

4.3 Health screening: Some procedures may require participants to be screened for risk factors. Appendix A is a screening questionnaire that must be used where indicated for the approved procedures in Section 6.

4.4. Consent: In general, a written consent for is required, but oral consent may be sufficient where the procedures are trivial and/or the participants are from within the School and familiar with the procedures (see Section 2.2.8).

4.5. Payment: Participants must never be bribed to participate. Consent may be invalidated if it is elicited by financial inducement or coercion, actual or implied. In other words, anything that might persuade people to take part in an investigation against their better judgement. Any payment made to volunteers should be for expenses, time, or inconvenience and all payments must be disclosed and approved by the Research Ethics Committee.

4.6. Chaperones: Investigators must be sensitive to the possibilities of sexual harassment, or the simple embarrassment, involved in a procedure. This is especially important where investigators and participants are closeted together or working alone after hours, as well as more obvious situations involving states of undress and fixing electrode to the skin. In these circumstances a chaperone must be present and the participant should be given the opportunity to have an operator of the same sex to fix electrodes and make measurements.

4.7. Records: Full records must be kept of the participants together with the information and consent forms, any health screen and details of payments to participants. Records must also be kept of experimental outcome and any adverse responses, bearing in mind the requirements of confidentiality and the Data protection Act. Any adverse responses or mishaps must be reported to the Chair of the Research Ethics Committee immediately.

5. WELFARE OF RESEARCH PARTICIPANTS

Regardless of the discipline within which researchers operate, they are expected to treat participants' emotional, physical, and psychological wellbeing as a priority when conducting research. There are a number of key points that should be made here.

- 5.1.** Researchers should be sensitive to conflicts of interest that might arise from the researcher-participant relationship;
- 5.2.** Researchers should consider their research from the standpoint of research participants in order to eliminate potential risks to psychological well-being, physical health, personal values, or dignity;
- 5.3.** Researchers should ensure that there are no individual factors that might reasonably lead to harm and they should inform research participants of any special action they should take to minimise such risks;
- 5.4.** Researchers should refrain from using financial compensation or other inducements that might encourage participants to risk harm beyond that which they face in their normal lifestyles;
- 5.5.** Researchers should obtain the approval of independent advisors whenever concluding that harm, unusual discomfort, or other negative consequences may follow from research, and obtain supplemental informed consent from research participants specific to such issues;
- 5.6.** Researchers should inform research participants from the first contact that their right to withdraw from the research at any time is not affected by the receipt or offer of any financial compensation or other inducements for participation;
- 5.7.** Researchers should inform research participants when evidence is obtained of a psychological or physical problem of which they are apparently unaware, if it appears that failure to do so may endanger their present or future wellbeing;
- 5.8.** Researchers should debrief research participants at the conclusion of their participation, in order to inform them of the outcomes and nature of the research, to identify any unforeseen harm, discomfort, or misconceptions, and in order to arrange for assistance (e.g., counselling) as needed; and

6. STORAGE OF SENSITIVE, PRIVATE AND CONFIDENTIAL INFORMATION

All research conducted will invariably yield data, and these data – including the participant's identity – must be treated as confidential. To this end, the researcher should:

- 6.1.** obtain the permission from the participant before recording their voice or image, to include their recorded oral consent;

- 6.2. store all data in accordance with the Data Protection Act (1998), and make explicit these storage procedures to the participant;
- 6.3. ask participants to give permission for the possible use of direct quotes from what they say, even though such quotes will be anonymous; and
- 6.4. ensure that participants are not identifiable in any subsequent publications, communications, writings, lectures, etc.

Web Links

Organisation	Web link
British Educational Research Association	http://www.bera.ac.uk/guidelines.html
Central Office for Research Ethics Committees (COREC)	http://www.corec.org.uk/
Her Majesty's Stationery Office (Data Protection Act, 1998)	http://www.hmso.gov.uk/acts/acts1998/19980029.htm
The American Psychological Association	http://www.apa.org/ethics/
The British Psychological Society	http://www.bps.org.uk/index.cfm

7. THE RESEARCH ETHICS COMMITTEE

The Committee will promote the highest standards of safety and ethical conduct within the School. Compliance with School and University Health and Safety policies is implicit in the conduct of all research and teaching within the School.

The Committee will, as appropriate, consider ethical issues raised by the teaching and research of the School and make recommendations to the School's Management Committee as to acceptable practice.

7.1 Composition

The School Research Ethics Committee is a sub-committee of the University Ethics Committee and shall have a membership consisting of:

- Chair
- Deputy Head Research
- Three representatives of the School (from different participant areas)
- Two PhD student representatives (one Education, one Sport Sciences)
- One representative from another School
- One representative of a partnership organisation

Applications not containing invasive or controversial procedures shall be considered by the Chair and approved by Chair's action. The Chair may call upon other members of the Committee for guidance, as appropriate. Applications referred by the Chair to the Committee for consideration will be reviewed first by an appropriately experienced member of the Committee in addition to two other members of the School. They will provide a report that will be considered by the Chair, or the full Committee, as appropriate. Decisions may recommend, on ethical grounds, either amendment or rejection of a particular proposal. The Committee shall also consider whether a protocol requires consideration by an external ethics committee, or whether it is beyond the scope of work of the School and should therefore be rejected

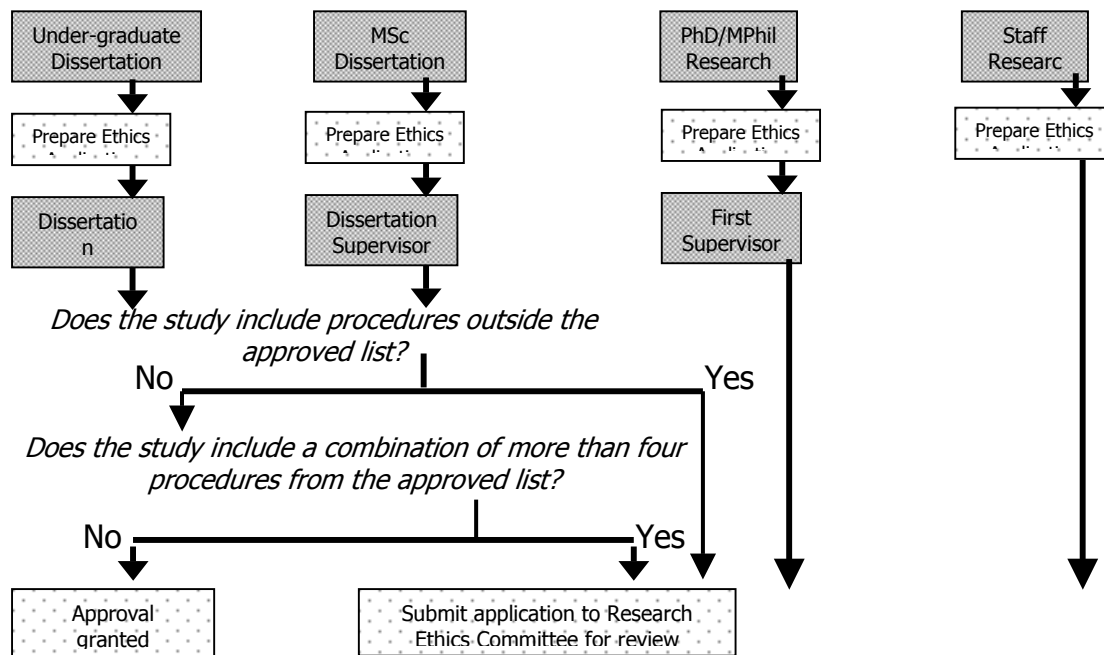
7.2 Terms of Reference

The Committee shall:

- Draw up guidelines for safe and ethical work with human participants in experiments and other methodologies concerned with teaching and research
- Consider applications for permission to carry out experiments and other methodologies involving human participants from members of staff, graduate students and, where appropriate, undergraduate dissertation students
- Keep under review all procedures involving human participants
- Consider any ethical or safety matters that are referred to it by other committees of the School

7.3 Procedures

The following flow chart illustrates the procedure for submission and consideration of applications to the Research Ethics Committee:



The Committee shall meet once in each term and otherwise as necessary. Between meetings the work of the Committee shall be divided between sub-groups made up from the membership, plus appropriately experienced members of the School (see above).

Submissions to the Committee must in all cases be made on the application form located in the Ethics section of WebCT. This should be returned to Carol Bark, School of Sport and Education.

Where staff are undertaking collaborative research, and protocols have already been approved by an appropriate external Ethics Committee, copies of the application and approval letter should be sent to the Chair. If the collaboration necessitates measurements that are in addition to those already approved, a separate application should be made the School Research Ethics Committee for approval of these procedures. To be considered in this way, the standards of the External Committee must be at least equal to those of this University.

On approval, applications will be filed and allocated an approval number.

Where appropriate and where the proposed protocol involves patients (except people with asthma aged between 18 to 65 yr who are habitual exercisers, and who have access to bronchodilator medication), children, people over 65 yr, or the use of invasive measurement techniques (except blood sampling and measurement of oesophageal and gastric pressures by suitably experienced/qualified personnel), the Committee will refer it for consideration by the University's Ethics Committee.

7. RESEARCH IN SOCIAL SCIENCE AND EDUCATION

Researchers in the School whose work is based in the social sciences should refer to guidelines produced by the appropriate academic association, e.g. British Sociological Association, British Educational Research Association or British Psychological Society. Applications for approval of research projects in these areas should demonstrate that appropriate guidelines have been consulted, that they have informed the application and will also inform subsequent research practice. The following websites should be consulted.

http://www.britisoc.co.uk/new_site/index.php

<http://www.bera.ac.uk/guidelines.html>

http://www.bps.org.uk/the-society/ethics-rules-charter-code-of-conduct/ethics-rules-charter-code-of-conduct_home.cfm

8. PROCEDURES APPROVED BY THE RESEARCH ETHICS COMMITTEE

Where participants are healthy and between the ages of 18 and 65 years (some procedures are restricted to those <30 yr), the Research Ethics Committee has approved the following procedures. These procedures are acceptable providing they are carried out in accordance with the School's Code of Practice on Experimentation Involving Human Participants and are fully supervised by an appropriately qualified academic member of staff. Appropriately qualified is taken by the Research Ethics Committee to mean a person who has received formal training and whose competence has been assessed by a person or organisation approved to do so. For example, in the case of venous blood sampling completing a course in the clinical skills training unit of a hospital. Persons qualified in this way will normally be expected to produce a certificate to confirm their training. Where procedures have been learnt in laboratories at other institutions, or at this University, a letter of recommendation from the head of that laboratory attesting to the competence of the individual and the number of procedures successfully completed by her/him will suffice. Although the individual procedures are acceptable, staff should bear in mind that a combination of a number of investigations may become contentious and advice should be sought from the Chair of the Research Ethics Committee. **In addition, it should be noted that for all procedures listed below, a thorough risk and safety assessment needs to be performed (see Section B in the School's Code of Practice on Experimentation Involving Human Participants). This assessment is subject to ethical approval by the School's Research Ethics Committee.**

8.1 Approved Procedures for Biomechanical Research

- **Video measurements.** Using video to obtain kinematics measures (position, velocity, acceleration) of the locations of the body joints of a participant. The participant may have markers attached to the surface of their body or to their clothes to aid identification of the body joints. **Where the participant is identifiable on a video, confidentiality must be guaranteed in accordance with the School's Code of Practice on Experimentation Involving Human Participants.**
- **Force measurements.** Using surfaces or equipment that is fitted with a force transducer to measure the forces exerted by or on a participant.
- **Pressure measurements.** Using a pressure platform or clothing insert to measure the external body pressure experienced by a participant.
- **Velocity measurements.** Using timing gates, laser gun, radar gun or similar devices to measure the speed of a participant, sports implement, or sport vehicle.

- **Acceleration measurements.** Using an attached accelerometer to measure the acceleration of a participant, sports implement, or sport vehicle.

8.2 Other Approved Procedures

- **Anthropometry.** Measurement of height, weight and body segments. Body fat estimations by skin fold callipers and bioelectrical impedance (18-65 yr: See section 4.6)
- Measurement of **aural or rectal temperatures** using thermistor probes (18-65 yr: see section 4.6)
- Measurement of **skin temperature** using thermistor probes or other non-invasive methods (18-65 yr: See section 4.6)
- Measurement of **systemic blood pressure** by non-invasive methods (18-65 yr)
- Recording **electrocardiogram**, including 24 hour continuous recording involving chest electrodes and associated electrical equipment (18-65 yr: see section 4.6)
- Recording an **echocardiogram**, including parasternal, supra-sternal and sub-costal views both at rest and during exercise (18-65 yr: see section 4.6)
- Measurement of **heart or breathing sounds** using a microphone (18-65 yr: see section 4.6)
- **Ambulatory measurement** of cardiac function or breathing (18-65 yr)
- Measurement of cardiac function by **impedance cardiography** (18-65 yr: see section 4.6)
- The following tests of **autonomic function**: Valsalva Manoeuvre, Orthostasis tolerance test. The measurement of baroreflex sensitivity using external neck suction by means of a specially constructed airtight collar connected to a vacuum pump. A general health screen is required prior to these procedures (Appendix A) and the procedure monitored as for exercise testing (Section 7: 18-30 yr)
- Measurement of **limb blood flow** by venous occlusion plethysmography using strain gauges to measure circumference of the limb and by Doppler ultrasound. Occluding cuffs at wrists and ankles, where used, to be inflated to systolic pressure + 13kPa for up to 15 minutes. Measurement by photoelectric pulse sensor and Doppler ultrasound is also permitted (18-65 yr)
- **Blood sampling** by puncture of an upper limb vein by either a qualified medical practitioner or a person trained to perform the procedure. There should be no more than 4 venepunctures during one day, drawing no more than 20 ml of blood per sample, and for no more than 3 consecutive days. Sampling must be carried out in accordance with Code of Practice for handling Body Fluids (Section 6: 18-65 yr)
- **Capillary blood** sampling from finger or ear lobe using a sterile lancet. There should be no more than 5 punctures made in any one session. Sampling must be carried out in accordance with Code of Practice for handling Body Fluids (Section 6: 18-65 yr)
- **Sampling of saliva** using cotton wool swabs. Sampling must be carried out in accordance with Code of Practice for handling Body Fluids (Section 6: 18-65 yr)

- Measurement of **ventilation and gas exchange**. Participants may breathe through a face mask or a rebreathing bag, tube or valve box with mouth piece and nose clip or ventilated hood. Inspiratory and expiratory resistances should be minimal (18-65 yr)
- Administration of **gas mixtures** other than air including rebreathing from a closed system with or without a CO₂ absorber in the line. With the exception of inspired gas mixtures where the normal N₂ component is replaced with He (21% O₂) the inspired mixture will not contain gases other than found in room air. For tests in which participants are required to breathe the mixture for more than 1 minute the mixture will contain no more than 5% CO₂ and no less than 10% O₂. For tests in which participants are required to breathe the mixture for less than 30 seconds (e.g., measurement of cardiac output using CO₂ rebreathing), the mixture will contain no more than 12% CO₂, with the balance O₂. Inspired mixtures must be checked by gas analysis and a senior investigator must be present whilst the mixture is administered. All gas mixtures will be checked by an experienced senior investigator who will supervise the administration. The addition of external dead space or an added resistance to the breathing circuit is permitted at rest and during exercise, provided that participants are able to remove the dead space or resistance, and that in the case of added dead space, alveolar PCO₂ is monitored continuously (18-65 yr). Two observers must be present during these procedures.
- **Respiratory manoeuvres**. Voluntary breath holding may be studied providing participants have immediate access to room air and can make adequate respiratory movement should they so wish. Participants may be asked to make forced expirations or similar actions and hyperventilate, providing the end-tidal PCO₂ does not fall below 3kPa. Paced breathing is also permitted (18-65 yr). Participants may be asked to make maximal forced expiratory and inspiratory efforts against an occluded airway to measure respiratory muscle strength. Participants may also be asked to breathe against a progressively increasing external inspiratory or expiratory resistance until volitional fatigue of their respiratory muscles. In all cases participants should be able to remove the obstruction or resistance themselves (18-65 yr).
- **Measurement of ventilation** using a nasal thermocouple or by inductance plethysmography.
- **Respiratory system resistance** measured using a body box, an interrupter or forced oscillator system (18-65 yr)
- **Respiratory muscle pressures** using oesophageal and gastric balloons by appropriately experienced personnel. Balloons should be passed nasally into the lower third of the oesophagus and stomach after the application of <1ml local anaesthetic (2% lignocaine hydrochloride) (18-30 yr)
- Respiratory motor output using mouth occlusion pressure (18-65 yr)
- Measurement of **electromyographic activity (EMG)** by surface electrodes. (18-65 yr: see section 4.6)
- Measurement of **skin conductance** using surface electrodes (18-65 yr: see section 4.6)
- **Exercise testing** using treadmills, cycle or other ergometers to volitional fatigue and in accordance with the School guidelines. In addition, participants may be asked to perform incremental shuttle running to volitional fatigue. For exercise over 50% VO₂max two observers must be present and over 70% there must be a person on hand trained in the administration of CPR. Testing should be limited to a total of two hours of exercise. Participants require a general health screen (Appendix A) (Section 7: 18-30 yr)

- **Eccentric exercise** designed to cause delayed onset muscle soreness (**DOMS**) and/or damage should be limited to 40 minutes stepping off a bench at knee height (18-30 yr)
- Measurement of **maximal power output**, e.g., Wingate testing, provided that a person trained in the administration of CPR is on hand. Participants require a general health screen (Appendix A) (Section 7: 18-30 yr)
- Standing vertical or horizontal jumps may be used to assess **leg power** (18-65 yr)
- Participants may be requested to **sprint** maximally (18-30 yr)
- **Muscle function testing.** Isometric, isokinetic or dynamic muscle function testing of upper and lower limb muscles using voluntary or electrically evoked contractions. Use of free weights or isokinetic dynamometry (concentric and eccentric contractions). Electrical and magnetic activation of limb muscles using percutaneous electrical stimulation or percutaneous stimulation of motor nerves, excluding prolonged tetanic stimulation of the femoral nerve (twitches and < 1 s tetani are acceptable). The phrenic, thoracic and lumbar nerves may be stimulated but only with twitches or brief tetani. Testing may be carried out under ischaemic conditions but this should not be maintained for more than 15 minutes. In all testing the intensity and duration of the contractions should be limited by the discomfort experienced by the participants and the School guidelines (Section 8) should be followed strictly. For tests involving maximum voluntary contractions of major muscle groups the age range is 18-30 yr. For older participants a health screen is required. Submaximal efforts and use of smaller muscle groups, 18-65 yr
- **Transcranial magnetic stimulation** of muscles by appropriately experienced operators (18-65 yr)
- Measurement of **blood and tissue oxygenation** using transcutaneous optical methods (18-65 yr)
- **Measurement of joint angles and muscle length, tremor and passive mechanical properties** during movement using goniometry, video or ultrasound recording techniques, or with accelerometers (18-65yr)
- Imaging of muscle structure using **ultrasound** recordings (18-65 yr)
- Protocols involving **strength or endurance training**, provided they are properly supervised. Participants require a health screen (Appendix A: 18-30yr)
- **Urine collection** (Section 6: 18-65yr)
- **Manipulation of diet.** Overnight or 36 hour starvation, but with fluids *ad libitum*. Modification of carbohydrate and fat content of the diet for no more than three days. Participants require a health screen (Appendix A: 18-65yr)
- Taking **sodium bicarbonate/citrate or ammonium chloride** at no more than 0.3 g/kg body mass for no more than 3 days. Participants require a health screen (Appendix A: 18-30yr)
- Taking **dietary supplements** that are available over-the-counter and taken in accordance with manufacturers recommendations. Participants require a health screen (Appendix A: 18-30yr)

Procedures requiring appropriate experience or training may be performed by those not in possession of such experience or training under supervision of an experienced or qualified person.

9. CODE OF PRACTICE FOR HANDLING BODY FLUIDS

INTRODUCTION

This Code of Practice is concerned with the range of potential hazards that exist within the School's activities from Hepatitis 'B' and the Human Immunodeficiency Virus (HIV) (or Lymphadenopathy-Associated Virus (LAV)/ Human T Cell Lymphotropic Virus Type m (HTLV III) virus) which is responsible for AIDS.

HIV can be transmitted by blood, blood products, semen, vaginal secretions and possibly other bodily fluids containing visible blood - the virus has also been isolated from saliva, tears, urine, breast milk and brain tissue. **However, it must be stressed that HIV is not readily transmissible, the main risk to workers in this School being through accidental percutaneous inoculation from infected blood by contaminated needles and sharps of all descriptions. There is good evidence that infection from such accidents in laboratories and in hospitals treating AIDS patients is extremely rare.**

PROCEDURES

The following identifies areas of potential risks and describes "universal precautions and procedures" to be followed by all personnel whose work brings them into contact with human body fluids both inside and outside of the School. The training and the handling procedures to be adopted by students and research staff will be the responsibility of the member of staff concerned with the work.

LABORATORY COATS OR SIDE FASTENING GOWNS MUST BE WORN AT ALL TIMES. Disposable gloves MUST be worn by staff and students when **handling body fluids or materials that may have been contaminated with body fluids**. Particular care should be taken to cover any cuts on the hands. Use WATERPROOF dressings (available in all Laboratory First-Aid kits).

BLOOD SAMPLING - High risk area.

a) **Venipuncture and intravenous cannulation** to be carried out only by trained staff who are certified for these procedures. NEVER re-sheath needles. NEVER re-use needles or cannulae. When handling blood samples ALWAYS WEAR GLOVES.

b) **Finger Prick or ear lobe sampling** may be carried out by other laboratory users after instruction from staff in charge of the laboratory and only with continuing supervision. ALWAYS WEAR GLOVES. NEVER reuse autolets or lancets. NEVER carry out pipetting by mouth. If containers/vials become externally contaminated, clean immediately with 5% soluble Sodium Hypochlorite.

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| FAECES | - Low risk area although haemorrhoidal blood could be a possible hazard - WEAR gloves. |
| URINE | - Low risk area although menstrual blood could be a possible hazard - WEAR gloves. |
| SALIVA | - Low risk area although bleeding gums and mouth sores could be a possible hazard from participants using mouthpieces - WEAR gloves when handling used mouthpieces. After use clean and sterilise. See STERILIZATION PROCEDURE. |

NB. Protective eyewear should always be worn during procedures that are likely to generate splashes of any body fluids containing visible blood.

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| THERMOMETERS | - Low risk area - allocate 1 thermometer per person. |
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(GLASS)	DO NOT use for more than one person without sterilisation. After use clean and sterilise. See STERILIZATION PROCEDURE.
THERMOMETERS (RECTAL PLASTIC COATED PROBES)	- Low risk area. After use PARTICIPANTS first wipe clean and wash with soap and water. Place to soak and sterilise (as for STERILIZATION PROCEDURE). See DISPOSAL for any cloths, swabs or paper towels used.
SKIN SURFACE ELECTRODES (ECG, EEG & EMG)	- Low risk area. Source of risk - exudates, capillary haemorrhage from skin abrading. If abrading WEAR GLOVES. Equipment hazards: disposable electrodes, electrode swabs, orange sticks, tape, paper bench-cloths. DISPOSE of these IMMEDIATELY after FIRST use. NEVER share. Use ONCE ONLY. a) Razors, needles, in "SHARPS bin" b) Remainder - see DISPOSAL. STERILIZE non-disposable electrodes after every use. Each participant must remove his/her own electrodes, immediately wash them - in the approved manner - and then place them in the prepared disinfectant, as directed by the staff. Then follow STERILIZATION PROCEDURE.
SKIN NEEDLE ELECTRODES	- High risk area , to be carried out only by suitably qualified staff. In normal circumstances these are BANNED from use in this School. In all circumstances an application for use should be made only through the University Ethical Advisory Committee.
SPIROMETRY	- Low risk area. The only recommendation at present is that the water in water-trap spirometers is drained immediately after use and the spirometer left to dry. Valves and mouthpieces - after use see STERILIZATION PROCEDURE.
STERILIZATION PROCEDURE	- PARTICIPANTS first wash their own equipment with soap and water. Next use freshly activated Sodium Hypochlorite 10,000 ppm available chlorine. Soak for 1 hour, rinse and air dry. See DISPOSAL for any cloths, swabs or paper towels used.
SPILLAGES	- If any body fluid is spilt clean down using Sodium Hypochlorite 10,000 ppm available chlorine and disposable paper towels (see DISPOSAL below) - WEAR gloves. Contact with mucous membranes - wash freely in running water and have EYE wash bottles available (solution in these bottles must be changed weekly).
DISPOSAL	- ALL SHARPS must be placed in a 'SHARPS BIN' (puncture proof) and INCINERATED (as is present day practice). - ALL contaminated material, i.e. cloths, swabs and paper towels containing blood, other body fluids and faeces, should be bagged in yellow clinical waste plastic bags and bags stored in suitable marker areas for collection

- FIRST-AID
- Accidents where blood is present, e.g. cuts - wash under running water with soap or an antiseptic suitable for skin. ENCOURAGE BLEEDING. Clean surfaces, where contaminated with blood, as for SPILLAGES.

ALL ACCIDENTS involving **inoculation or cuts and possible contamination from** body fluids MUST be reported by the individual concerned to the ACADEMIC MEMBER OF STAFF with overall responsibility for the work. ACCIDENTS of this nature MUST BE RECORDED in the DH Accident Book B1510. Additional advice, where necessary, will be available from the **University Medical Officer**. The members of staff will be responsible for ensuring that accidents are reported to the School Safety Officer who will ensure the appropriate form is completed and submitted to the University Health and Safety Officer as soon as possible.

10. CODE OF PRACTICE FOR EXERCISE TESTING

CONTRA-INDICATIONS TO EXERCISE Participants with known resting pathological abnormalities, resting heart rate greater than 100 beats per min, blood pressure greater than 170 over 100 mmHg, resting body temperature outside the range 37.5-38°C (98-100°F), acute infectious diseases (of common diseases, influenza is particularly dangerous), or recent history cardio-respiratory disease should not be tested. Neither should participants who have had a recent heavy meal or have been drinking alcohol. These conditions should come to light during discussion with the participant whilst explaining the procedure and when the health screen questionnaire (Appendix A) is administered.

INDICATIONS FOR STOPPING EXERCISE include participant's volition, sustained maximum heart rate (maximum for the age), pain in the chest (angina), cramp-like pains in the legs (claudication), signs of collapse, pallor, cold moist skin, cyanosis, staggering, confusion.

BEFORE EXERCISE, all unnecessary equipment, chairs, stools, clothing, briefcases etc. must be cleared well away. The necessary apparatus must be kept to a minimum, must be checked in advance to minimise malfunctions and must be checked for electrical safety (see section on electrical safety). There must be sufficient space for the participant to be laid on the floor if they feel faint at any time during or after the exercise. The participants must have the situation and protocol fully explained.

DURING THE EXERCISE the participant must be watched at all times for signs of inattention or tiredness. Distractions by others must be prevented.

AT THE CESSATION OF EXERCISE, the laboratory situation sometimes requires a sudden end to a bout of exercise. This can cause faintness, dizziness or collapse. A continuing period of gentler exercise, i.e. a warm down should be provided if at all possible, particularly after strenuous effort of more than a brief duration. If the participant faints or feels dizzy they must be laid on the floor with knees raised.

PERSONNEL REQUIRED: If the exercise is greater than 50% VO₂max there must be two observers present, one to attend to the measurements whilst the second observes the participant. Over 70% VO₂max there must be one person trained in CPR on hand. "On hand" means no further away than the next room.

10.1 Treadmill exercise

Investigators must have received instruction on the use of the treadmill and demonstrate they are competent before using it with participants.

Two observers are required, one observer must remain at the treadmill control panel whenever the participant is on or near the treadmill or connected to ancillary equipment and it

may be necessary to have one spotter at the rear of the treadmill to warn the participant if they are moving too far to the side of the belt.

Before switching on the power check that there is nobody on the treadmill belt and surround. Switch on the belt to see if the treadmill has been left at the recommended safe walking speed. If this is not the case, reduce the speed to 4kph.

Check the operation of the controls, i.e. the operation of stop buttons, the brake setting, the speed increase and decrease, and the incline, if these are to be altered during the experiment. Report any faults as the machine may not be in a safe condition. Check that safety mats are in place at the end of the treadmill belt.

Instruct or remind the participant on:

- i) the position and method of operation of the stop buttons.
- ii) the change in walking pattern to be adopted by inexperienced users, i.e. to take longer than usual strides and to look up
- iii) the indications for stopping exercise
- iv) the procedures of the experiment if the participant has not used the apparatus before.

Allow the participant to practice walking on the treadmill. If the participants are naive users they should make use of the handrails and consider using a safety harness where feasible.

10.2 Stepping exercise

The preceding sections all apply. As there is an increased risk of falling, extra care must be taken in clearing away any unnecessary encumbrances from the vicinity of the exercise test and in watching the participant for inattention, tiredness etc.

10.3 Cycle Ergometry

Cycle ergometry avoids the risks of falling inherent in both (a) and (b) above. Nevertheless, the participant must always be watched and monitored in the same ways at all times.

When participants are exercising on constant velocity ergometers, particular attention must be paid to the arrangements for emergency halts, especially when high pedalling speeds are used.

11. CODE OF PRACTICE FOR MUSCLE FUNCTION TESTING AND ELECTRICAL STIMULATION

Muscle function testing involving voluntary contractions involves few risks provided the investigators are familiar with the equipment. Electrical stimulation must only be undertaken with equipment that has been approved for human use and has a current test certificate. The main concerns are to limit the pain and discomfort to the participants. The cathode should be used over the motor point or motor nerve. When testing participants for the first time the current and frequency must be increased slowly to allow the participant to become familiar with the sensations and identify their limit of toleration. Care must be taken not to evoke large contractions of the unrestrained leg as rapid and violent movements can injure the lower leg and/or knee. Similar care must be taken when using either percutaneous stimulation of the muscle or of the motor nerve. Prolonged (>1 s) tetanic stimulation of the femoral nerve may only be undertaken in exceptional circumstances.

School of Sport and Education

Health Questionnaire

Name:

Address:

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Phone:

Name of the responsible investigator for the study:

Please answer the following questions. If you have any doubts or difficult with the questions, please ask the investigator for guidance. These questions are to determine whether the proposed exercise is appropriate for you. Your answers will be kept strictly confidential.

1	Are you female?		
2	What is your date of birth? Day.....Month.....Year..... Your age is years		
3	When did you last see your doctor? In the: Last week Last month.....Last six months..... Year..... More than a year.....		
4	Are you currently taking any medication?	Yes	No
5	Has a doctor ever advised you not to take vigorous exercise?	Yes	No
6	Has your doctor ever said you have 'heart trouble'?	Yes	No
7	Has your doctor ever said you have high blood pressure?	Yes	No
8	Have you ever taken medication for blood	Yes	No

	pressure or your heart?		
9	Do you feel pain in your chest when you undertake physical activity?	Yes	No
10	In the last month, have you had pains in your chest when not doing any physical activity?	Yes	No
11	Has your doctor (or anyone else) said that you have raised blood cholesterol?	Yes	No
12	Have you had a cold or feverish illness in the last month?	Yes	No
13	Do you ever lose balance because of dizziness, or do you ever lose consciousness?	Yes	No
14	Do you suffer from back pain? If so, does it ever prevent you from exercising?	Yes Yes	No No
15	Do you suffer from asthma?	Yes	No
16	Do you have any joint or bone problems that may be made worse by exercise?	Yes	No
17	Has your doctor ever said you have diabetes?	Yes	No
18	Have you ever had viral hepatitis?	Yes	No
19	If you are female, to your knowledge, are you pregnant?	Yes	No
20	Do you know of any reason, not mentioned above, why you should not exercise?	Yes	No
21	Are you accustomed to vigorous exercise (an hour or so a week)?	Yes	No

I have completed the questionnaire to the best of my knowledge and any questions I had, have been answered to my full satisfaction.

Signed:.....

Date:.....

Health Questionnaire:

Notes for the investigator

This questionnaire is for use in circumstances where you are intending to carry out a procedure that has been approved by the Research Ethics Committee, but where a health screen is indicated (see Section 6). Questions 3 and 4 should be used to test, discretely, the veracity of the other answers.

If your participant is within the age group specified (usually 18 to 30 years) and has answered NO to questions 5-20 and YES to question 21, you may include him or her in your study.

If you are using this, or a similar, questionnaire for participants outside this age range or with possible pathologies, you must have agreed with the Research Ethics Committee the criteria for accepting participants into the study and safeguarding their health.