



PRIFYSGOL
BANGOR
UNIVERSITY

**SCHOOL OF SPORT, HEALTH AND
EXERCISE SCIENCES**

**Ethics Guidelines and Standard Procedures for
Human Research**

September 2017

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Gellir cyfieithu'r cyhoeddiad hwn i'r Gymraeg os bydd galw am hynny

This publication can be translated into Welsh on request

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Introduction

SSHES is recognised nationally and internationally for the prowess of its research and strongly promotes the scientific study of sport, health and exercise. This is with the proviso that at all times our research is carried out in an ethical way which protects the rights and interests of participants. Particular emphasis is placed on minimising the risks to participants, ensuring that participants give informed consent, and respecting participants' privacy.

It goes without saying that SSHES expects all its members to observe the highest standards of conduct when engaged in research.

In recent years there has been a move to formalise the laws and practices relating to research using human subjects. This has meant an increased focus on ethical issues which might occur in individual research projects and, as with so much else of life today, an increase in bureaucracy. However the rights of anyone choosing to take part in research are now much better protected and researchers themselves are far more aware of ethical issues which might arise in the course of their research.

The ethical basis for all research is set out in The American College of Sports Medicine's policy statement regarding the use of human subjects and informed consent.

“By law, any experimental subject or clinical patient who is exposed to possible physical, psychological or social injury must give informed consent prior to participating in a proposed project. Informed consent can be defined as the knowing consent of an individual or his legally authorised representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress or other form of constraint or coercion.” (Appendix 4)

While informed consent is paramount to the ethical conduct of research, it is also vital that

- all risks to participants are kept to an absolute minimum
- that participants are treated humanely
- that participant's privacy is respected during the experiments
- that the findings are treated as confidential and kept anonymous
- that participants must be free to withdraw at any time without prejudice

These are the basic principles of ethically performed research and each of these aspects must be addressed in every research project.

Further information about ethics and research can be found in Appendices 1, 2, 3 and 4.

Appendix 1: The Declaration of Helsinki is a statement of the World Medical Assembly's Recommendations guiding Physicians in biomedical research involving human subjects. This is regularly updated, and is a statement of current international opinion on ethics and human research (Appendix 1).

Learned societies all have their own position on ethical issues. The positions of

- **BASES (British Association for Sport and Exercise Science);**
- **The British Psychological Society;**
- **American College of Sports Medicine;**

are set out in Appendices 2, 3 and 4 respectively.

The University Ethics Committee has established a Research Ethics Framework which applies to all research carried out at the University. This is accessible on the intranet site at:

<http://www.bangor.ac.uk/ar/ro/recordsmanagement/REF.php.en>

Definitions

The following terms are defined for the purpose of this document:

- 'Research involving human participants' (referred to as 'research') is broadly understood to include physical and psychological experiments; electronic or other kinds of observation in an experimental setting; surveys; and fieldwork.
- 'Researcher' or 'investigator' – these terms include undergraduates, postgraduates and staff.
- 'Participants' – this term signifies any person who provides primary data in the conduct of research and who is not acting in the capacity of researcher or assistant to the researcher. It also includes the terms “special participants” such as children or persons with physical impairments such as visual or hearing limitations.
- 'Informed consent' is the knowing consent of a participant (or legally authorised representative in the case of a child or a dependent person) who is in a position to exercise power of choice without any undue inducement or element of force, fraud, deceit or coercion.
- SSHES – School of Sport, Health and Exercise Sciences
- Children, minors and vulnerable adults; For the purposes of this document the following definitions apply
 - **Child** - A child is a person under 16 years of age. A person over 16 is able to give consent
 - **Minor** - a minor is a person under 18 years of age. The rules relating to police checks apply to all minors.
 - **A Vulnerable Adult** is a person over 18 years of age who:
‘... is, or may be, in need of community care services by reason of mental or other disability, age or illness and who is, or may be, unable to take care of himself or herself, or unable to protect himself or herself against significant harm or serious exploitation.’¹

The University Ethics Framework considers vulnerable people as those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.

¹Who decides? Making decisions on behalf of mentally incapacitated adults, Law Commission, 1997

Policy

- The SSHES Ethics Committee will ensure that research performed under the aegis of SSHES is conducted in an ethical and humane manner.
- The ethical implications of every project will be assessed and addressed in the protocol of the project.
- No research shall be carried out at SSHES without going through the ethical approval process.
- All participants will be provided with an information sheet and will be asked to give informed consent.
- ALL projects involving human tissue, NHS patients, medical/clinical treatment, or exposure to radiation will be referred to the Betsi Cadwaladr University Health Board - West Ethics Committee (EC).
- If the SSHES Ethics Committee has doubts about the ethical validity of a project it can refer to the Betsi Cadwaladr University Health Board - West EC or The University Ethics Committee.
- If the researcher and the Ethics Committee cannot agree, the researcher is entitled to appeal to the University Ethics Committee (see Appendix 8).

Procedures

The Ethics Committee will oversee the process of obtaining ethics approval.

All proposals whether at undergraduate, postgraduate or staff level, will go through the Ethics process.

The ethical consequences of all undergraduate and MSc proposals will be assessed by the supervising staff member who will rate the project against the standards.

When the supervising staff member assesses a project as involving less than minimal risk (as defined on Page 22) they can provide ethics approval for the project.

All research projects involving more than minimal risk (as defined on Pages 23 and 24) will be referred to the Ethics Committee.

If an undergraduate or MSc project proposal undergoes major revision once it has received ethics approval, a new approval form must be submitted for the new study.

Where there is doubt about the ethical implications of a proposal it will be referred to the Ethics Committee.

The Ethics Committee

Membership

The Ethics Committee will consist of at least five members and include representatives from both psychology and physiology, plus a lay member and the member of the Registrar's Office with responsibility for Ethics. A SSHES PhD student representative may be appointed (advised) to act as the student representative on the committee. In some instances where necessary expertise is warranted an external expert may temporarily act as part of the committee.

A chairperson will be appointed from the members.

Terms of Reference

- 1 To ensure that appropriate written procedures are in place to enable research activity in the School of Sport, Health and Exercise Science (SSHES) to comply with agreed ethical practices as detailed in the School's Ethics Guidelines and Standard Procedures for Human Research with the object of minimising the risks of harm to all persons engaged in research.
- 2 To regularly review procedures as described in the School's Ethics Guidelines.
- 3 To receive and make recommendations concerning all research proposals which have been categorised as involving more than minimal risk by the staff who have reviewed the proposal.
- 4 To receive and make recommendations about other research proposals which might be categorised as involving more than minimal risk.
- 5 To receive and make recommendations concerning all research proposals where the ethical consequences are in doubt.
- 6 To ensure that all risks associated with any proposed research activity have been fully considered by the investigator(s) involved.
- 7 When NHS patients, medical treatments, storage of human tissues/cells, or exposure to radiation are involved, assessment of the proposal will be passed on to the Betsi Cadwaladr University Health Board – West Research Ethics Committee.
- 8 When other complex issues are identified the committee can consult The University Ethics Committee.
- 9 If a researcher chooses to appeal against the decision of the SSHES Ethics Committee, the project shall be referred to the University Ethics Committee which has procedures in place to deal with such an appeal (see Appendix 8).

10 All members should regularly attend the Ethics education sessions which are offered by the University Ethics Committee.

Frequency of meetings

The University Research Ethics Framework requires School Ethics Committees to meet at least every six months.

Reporting to

- University Ethics Committee

A copy of the minutes of meetings will be sent to:

- Head of School
- Board of Studies

NB – Health and Safety Issues

While health and safety issues are of vital importance for the safe conduct of research, they are separate from ethical issues. The Ethics Committee needs to be assured that health and safety measures are in place for procedures used in any project. A risk assessment should be performed and a risk management programme instituted. However, the detail and application of such procedures and practices are the responsibility of the SSHES Safety Co-ordinator, not the Ethics Committee. Please refer to the Safety Co-ordinator in the first instance.

The Process of seeking Ethics Committee Approval for a Project

Rationale

As a researcher you have a professional and moral responsibility to adhere to ethical principles and procedures as well as the code of conduct appropriate to your respective discipline.

Funding agencies will only sponsor research involving human participants which has been scrutinised by an Ethics Committee and successful accreditation of physiology laboratories depends on there being ethics guidelines in place. Furthermore leading scientific and medical journals will not publish studies unless they have received approval from an Ethics Committee.

The Ethical Implications of Individual Research Proposals

When you are planning a research project one of the first steps is to consider its ethical implications. You should use the following headings to do this

- 1 Humane treatment of participants
- 2 Respect for participant's privacy during experiments
- 3 Informed consent
- 4 Risk assessment
- 5 Risk minimisation
- 6 Confidentiality of findings
- 7 Maintenance of participant's anonymity
- 8 Participant feedback

In your protocol, and when you write up your project, you should have a special heading for ethical implications. If there are no ethical implications this should be stated.

For more detail on these headings, please see sections below:

1 Humane treatment of participants

It, of course, goes without saying that participants will be treated in a humane way at all times and every researcher sets out with this goal. However, there may be times when the desire to finish an experiment or to recruit another participant comes into conflict with treating the participant in a humane and ethical way. It is important to acknowledge that such conflicts occur in all types of research and if there is doubt, you should resist temptation and veer on the side of humane and ethical treatment. If doubt remains, the issue should be discussed with your supervisor or a member of the Ethics Committee.

It is often helpful for you to put yourself or a close relative in the position of your participants and see what you or your family members would think about what you are asking your participants to do.

2 Respect for participants' privacy during experiments

Privacy refers to the physical, social, psychological and spiritual aspects of a participant's life. Individuals are very different and what may be perfectly acceptable to one person may be considered as a gross invasion of privacy by another. As a researcher it is important that you are aware of this and that you are sensitive to the varying needs of your participants.

Physical privacy is the most obvious aspect of privacy. Participants should have a private area in which to change. If they are required to appear nude (for example when being weighed) the procedure should be performed by the participant or sensitively by a member of the appropriate gender. Special care should be paid to procedures involving invasion of personal privacy such as inserting rectal temperature probes. In some cases it may be in the best interests of both researcher and participant to have a third person present to act as a chaperone.

Many aspects of an individual's social, psychological and spiritual life are also private and, although they are not as obvious as physical privacy they too must be respected. Ethnic, religious and cultural factors influence beliefs and behaviours and need to be respected. You should always be on the look out for behaviour and body language that suggest invasion of privacy. If there is any doubt you should ask your participants whether they have any concerns.

3 Informed consent

Nowadays research cannot be conducted unless participants are fully informed of what they are letting themselves in for. Your participants must know what is going to happen to them, what risks they are being exposed to, how much time they must give up as well as what the research is about and how it will increase our understanding.

The participant should be given information by both word and mouth. Remember many members of the public find reading difficult and take special care when English is a second language. When using an information sheet it is usual to give the participants 24 hours or more to think things over and to ask their friends, family and even their GP for their views.

The School has adapted the Canadian Society for Exercise Physiology's Physical Activity Readiness Questionnaire (PAR-Q) (see Summary of Forms) or persons undertaking research which requires moderate to high-intensity physical activity. If participants are in any doubt after completing the questionnaire, they are advised to consult their doctor prior to performing any intense physical activity.

In addition, the participant should be asked if there are any parts of the information sheet they do not understand and at the end ask if they have any other questions.

Please see also the protocol SOP 12 – Informed Consent on the SHES U:\ drive/SHES Lab SOPs and Risk Assessments

Principle

Potential recruits for all research projects should be in possession of sufficient information to allow them to choose whether or not they wish to take part.

Process

- All potential recruits will be provided with an information sheet describing the project and what the participant may expect.
- You should use the SSHES template for preparing an information sheet (see Appendix 5).
- It is usual that the participant is given at least 24 hours to think things over before being asked to sign the information sheet.
- All potential recruits will be informed that they are free to withdraw from the project at any time without having to give an explanation. This also applies when a payment has been made.
- All student volunteers will be informed that their decision to participate in or withdraw from an experiment will have no influence on the marks they receive, the outcome of their period of study, or their standing with their supervisor, other staff members, or with the School.
NB – This statement can be deleted from Form 2 when the participants are not from the University
- When the researcher is satisfied the participant is fully informed and has no more questions, the researcher will ask the participant to complete the generic SSHES form '**Informed consent to participate in a research project or experiment**' (Form 2).
NB – Form 3 should be used for minors and dependent people.

ALL researchers taking Informed Consent should be trained to do so and that training recorded in the training log on the SHES U:\ drive, Health and Safety.

Please see also the protocol SOP 12 – Informed Consent on the SHES U:\ drive/SHES Lab SOPs and Risk Assessments

- Both participant and researcher must sign these forms.

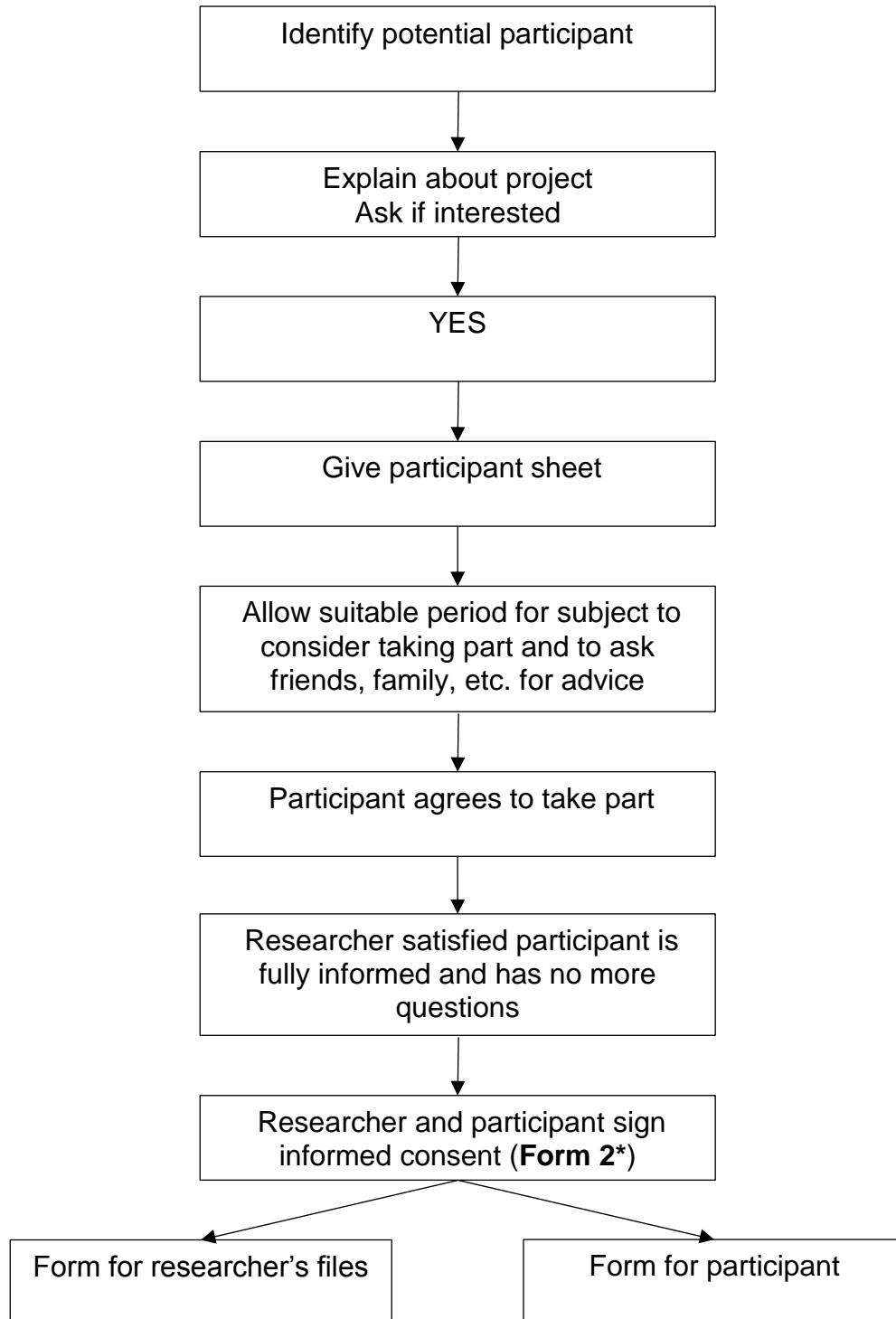
- Two forms should be signed; one for the researcher and one for the participant.
- The participant will be given an information sheet to keep.

See flowchart 1 '**Procedure for obtaining Informed consent from an Independent Person over Age 16**'.

If participants are under 16 or a dependent person, see Page 7 and Form 3

Flowchart 1 – Procedure for obtaining Informed Consent from an Independent Person over Age 16*

***NB –** If the participant is under age 16 or is a dependent person, see Page 7 and Form 3



Form for Informed Consent

Researchers should complete the generic SSHES form '**Informed consent to participate in a research project or an experiment**' (Form 2) and use this to document that the participant has read and understood the information sheet. The researcher is also required to sign this form. Two forms (one for the researcher's records and one for the participant) should be signed. See below for obtaining consent in minors or dependent populations.

Please see also the protocol SOP 12 – Informed Consent on the SHES U:\ drive/SHES Lab SOPs and Risk Assessments

Research involving children, minors or vulnerable people

All research involving children or vulnerable people must be referred to the Ethics Committee; see Page 7 for definitions of children, minors and vulnerable people.

Where possible, the consent of children and adults with impairments should be sought. Where research involves children under the age of 16, consent from parents or those in *loco parentis* (Latin for 'in place of parents') should be obtained. If research is to be conducted at a school for under 16s the head teacher can be counted as being in *loco parentis*. However, the Ethics Committee must be consulted in all cases. One of the reasons for this is to establish whether the head teacher's permission is sufficient or if parental consent is also required.

An information sheet is ALWAYS required.

The consent form for minors and dependent populations (Form 3) should be used.

Research involving concealment of information and deception

It may be impossible for some research to be conducted without withholding information (concealment) or misleading the participant (deception). This particularly applies to certain psychological study designs. All such studies must be referred to the Ethics Committee.

When, at the end of such an experiment, participants find out that they have been victim to specific types of concealment or deception they may understandably feel angry or humiliated at what the researcher has done to them. It is consequently of vital importance that if researchers anticipate the likelihood of such responses from their subjects, that they deal with these reactions when participants are debriefed and that there are measures in place to deal with such reactions.

The following applies to all research projects involving concealment or deception that may eventuate in subject's being angry or humiliated when made aware of the deception:

- All such studies require referral to the Ethics Committee.
- Researchers must assure the Ethics Committee that methods avoiding concealment or deception are not available to answer their research question.
- If information is withheld or deception is employed, debriefing **MUST** take place to protect the welfare and dignity of the participant.
- The researcher must ensure that the participant is informed that concealment or deception has taken place as soon as the experiment is finished.
- Measures to deal with all possible reactions by the participants should be in place.

The Information Sheet

This should be written in simple non-technical terms and be easily understood by a layperson. Use short words, sentences and paragraphs. The "readability" of any text can be roughly estimated by the application of standard formulae. Checks on readability are provided in most word processing packages.

Researchers at SSHES are advised to use a standard template when writing their information sheets. See Appendix 5 where you find a lot of useful advice on how to prepare information sheets for research projects.

Remember that the purpose of the information sheet is to give your potential participants enough information for them to know what they are letting themselves in for, what is going to happen to them, how much of their time you expect them to give up and what are the risks of the experiment (this includes risks to their dignity such as nude weighing and the use of rectal temperature probes).

After the reading the information sheet and receiving answers to their questions, participants should be in possession of enough knowledge to give fully informed consent.

4 Risk Assessment

Many of the routine procedures used in the laboratories at SSHES will have had risk assessment performed as part of the health and safety risk management regime. When this has been done it should be recorded in the protocol.

These are filed on the SHES U:\ drive/ SHES Lab SOPs and Risk Assessments and should be referenced in the Form 1 and supplemented with additional risk

assessments where necessary, or where no standard risk assessment is available, using the health and safety risk management process.

5 Risk Minimisation

Many of the routine procedures used in the laboratories at SSHES will have had risk minimisation performed as part of the health and safety risk management regime. When this has been done, it should be recorded in the protocol. Where it is not the case, researchers having carried out a risk assessment (see above), should put a programme in place to minimise the risks using the health and safety risk management process. This should be recorded in the protocol.

6 Confidentiality of findings

- It is of paramount importance for all SSHES researchers to preserve the confidentiality of all information acquired in their research.
- No information can be divulged without the prior written consent of the participant.
- Participants have the right to a copy of all information relating to them.
- The Data Protection Act 1998 applies to all research projects

Videotaping, audio-taping and photography

If a participant is to be videotaped, audio-taped or photographed in any manner, this **MUST** be disclosed in the information sheet.

The participant must be advised as to who will have custody of such tapes or photographs, how the tapes or photographs are to be used, and what will be done with them when the study is over.

7 Maintenance of participants' anonymity

Information about participants should be held in an anonymous manner.

Numbers or letters (rather than the name of the participant) should be used when data is stored.

8 Participant feedback

All participants in research should have the opportunity to feed back on their experiences. To this end a Participant Feedback Form (Form 6) is offered to allow participants to provide feedback on the conduct of the study to the Ethics Committee. This should be mentioned in the Information Sheet. It is optional for participants.

Gaining Ethical Approval for Research

Practices

- ALL research projects will be subject to the SSHES Ethics Approval process. **NB** – This applies to undergraduate, postgraduate and staff research projects.
- Any research involving storage of human tissue or cells, clinical procedures, NHS patients or staff, or exposure to radiation must be presented to the Betsi Cadwaladr University Health Board – West Ethics Committee.
- Undergraduate and MSc proposals will be rated by the supervising staff member at the time of the verbal presentation.
- Projects which fall within the criteria defined as “normally being considered as involving more than minimal risk” (see Pages 28 and 29) will be referred to the Ethics Committee.
- To avoid bias, all student project ethics approvals will be scrutinised by two independent members of staff in addition to the supervising staff member.
- All research projects will be registered on the SSHES Research/Ethics Register. This is maintained by the Senior Clerical Officer and is a public record.
- From time to time the Ethics Committee will audit the conduct of SSHES research.

The Ethics Review and Approval Form (Form 1)

This form serves two purposes:

- 1 Firstly, it asks a series of questions relating to the most common ethical issues which crop up in research projects at SSHES. These questions should be completed as part of the preparation and presented with the other documents listed in the table when the project is submitted.
- 2 Its other function is to document the fact that the project has been rated from an ethics point of view by the supervising staff member.

Procedures for all Undergraduate and Masters Projects

Please consult the relevant module handbook for specific guidance (See also Table 1)

- Researcher decides on research area and supervisor.
- Researcher collects **Ethics review and Approval Form** (Form 1) from the General Office or downloads from U:\ Drive or SSHES staff/student intranet. This form may also be available from part of the module Blackboard location
- Researcher completes Ethics review and Approval Form (Form 1).
- Researcher writes participant information sheet (for advice see Appendix 5).
- Researcher customises **Informed Consent Form** (Form 2) – if minors or vulnerable people use Form 3.

AT THE TIME OF PRESENTATION

- 1 Researcher will specifically detail whether there are any ethical issues or not. If there are, they should be acknowledged and discussed. This will be part of the marking process. However, because many projects are modified in the period between the presentation and starting the research, the final assessment will be done prior to starting the research. This is important for you to consider in the time between submitting an ethics document to your supervisor for the Year 2 Project Proposal module (JXH2002 / JXH2002) and submitting your ethics document for final ethical approval. At Year 2 the completion of these ethics forms (Form 1 and participant information sheet) are submitted as an appendices in your final project proposal submission for marking purposes only. You DO NOT require signatures on these forms at this point and it is extremely rare that these forms submission will be used in their present iteration for your actual ethical approval process in Year 3, no matter how highly scored they are. You should discuss this with your project supervisor early in Year 3.

PRIOR TO STARTING RESEARCH PROJECT

- 2 When the project is finalised, the researcher submits completed Ethics Review and Approval Form (Form 1), Information Sheet, customised informed consent form with project proposal (undergraduate) or independent study proposal (MSc) to the supervisor who with another staff member will assess the project with regard to its possessing “more than a minimal risk”.
- 3 If the project is decreed to possess “more than a minimal risk”, or if there are any other ethical issues it will be referred to The Ethics Committee. Otherwise the two staff members can conclude that the project involves less than minimal risk and sign the Ethics Review and Approval Form (Form 1).

The project should then be registered on the SSHES Research/Ethics Register, by stapling and taking ALL of your documents (see Point 2 above) to the Senior Clerical Officer (Mark Chitty) in the General Office. The applicant should also sign Form 1 before doing this.

NOTE: RESEARCH PROJECTS MUST NOT BE STARTED BEFORE ETHICAL APPROVAL HAS BEEN OBTAINED. I.E WHEN FINALISED FORMS ARE SUBMITTED TO THE GENERAL OFFICE

The Definition of 'more than minimal risk'

(See also *Procedure for projects rated as 'more than minimal risk'*, Pages 28 and 29)

- For the purposes of referral to the School Ethics Committees, the University has defined research projects falling into the following categories as involving more than minimal risk:
- Research involving NHS patients.
- Research involving people under 18 years, vulnerable people (see Page 7 for definition) or those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.
- Research into sensitive topics – e.g. participants' sexual behaviour, their illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.
- Groups where permission of a gatekeeper is normally required for initial access to members.
- Research involving deception which is likely to upset subjects, or activities which conducted without participants' full and informed consent at the time the study is carried out.
- Research requiring access to records of personal or confidential information, including genetic and other biological information, concerning identifiable individuals.
- Activities which might induce psychological stress, anxiety or humiliation or cause more than minimal pain.
- Intrusive interventions – e.g. the administration of drugs or other substances, vigorous physical exercise in people unaccustomed to it and deemed to be 'at risk', or exposure to extreme physical or psychological conditions.

These items are specified on the Ethics Review and Approval Form (Form 1) when the applicant is asked directly whether any of these conditions apply to the project.

If one or more of the conditions apply the project needs to be referred for consideration by the Ethics Committee.

If there is any doubt or other ethical issues arise, the project should also be referred.

Table 1 – General Procedure for Acquiring Ethics Committee Approval for Undergraduate and MSc Student Projects

NB – Please consult the relevant module handbook for very specific module guidance regarding deadlines, ethics workshop dates, and the implications of missing deadlines.

Process	Action	Documentation
Preparation	<ul style="list-style-type: none"> Decide on project and supervisor Write proposal Consider ethical implications of project with supervisor Write Information Sheet Customise Informed Consent Form 2 (Form 3 for minors and dependent persons) Is exercise involved? If so, adapt Forms 4 and 5 If minors and dependent persons are involved researchers will need to be DBS checked 	<ul style="list-style-type: none"> Completed Ethics Review and Approval Form (Form 1) Information sheet Consent Form 2 or 3 Completed Forms 4 and 5 (as necessary) See Disclosure and Barring Service – Procedures (Appendix 6)
Submission	<ul style="list-style-type: none"> Submit proposal Ethical aspects of the study will be considered as part of the marking process 	<ul style="list-style-type: none"> Proposal form (undergraduate) OR Independent study form (MSc) Ethics Review and Approval Form (Form 1) Information sheet Consent Form 2 or 3 Forms 4 and 5 (as necessary)
Before starting Research	<ul style="list-style-type: none"> Table all documents submitted (see above) Include information relating to questions on Ethics Review and Approval form (Form 1) in presentation. Supply ALL ethics documents to supervisor at least two weeks in advance of agreed deadline (Year 3 and MSci) or set module deadline (MSc). Supervising staff member assesses project using Ethics 	<ul style="list-style-type: none"> Completed Ethics Review and Approval Form (Form 1), participant information sheets and (modified) informed consent form

	<p>Review and Approval Form (Form 1)</p> <ul style="list-style-type: none"> • Supervising staff member grades risk profile of project • • Decide with supervisor on course of action for how additional signatures will be sought. For instance will the supervisor of the student seek additional signatures, will the signatures be sought by sending electronic versions or hard copy version of the ethics document to relevant staff? • In the event that the project represents greater than minimal risk and the project is not already approved as part of a larger research project, the supervisor should send all relevant documents to the SSHES research ethics committee during a corresponding SSHES ethics window rather than seeking signatures of approval from two additional staff members. 	
<p>Obtaining Ethics Committee Approval</p>	<ul style="list-style-type: none"> • See flow charts for projects graded 1) less than and 2) more than minimal risk 	<ul style="list-style-type: none"> • Study is enrolled on SSHES Research/Ethics Register

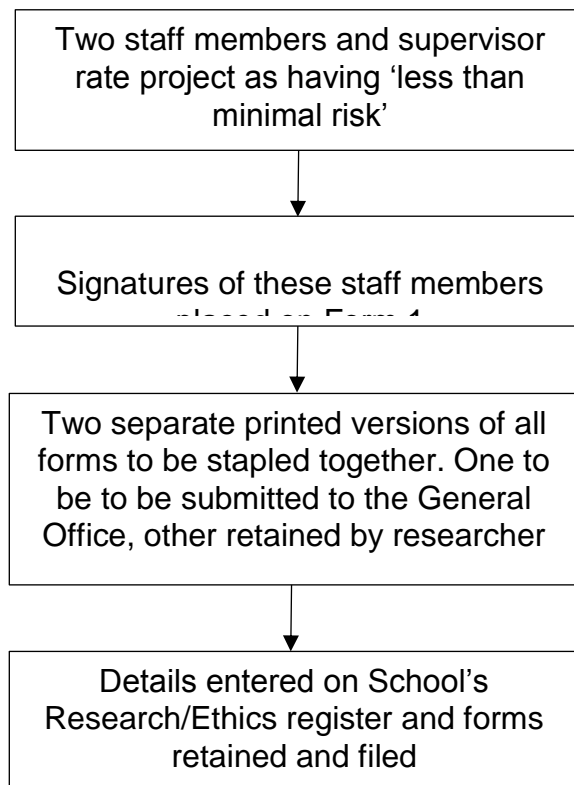
Procedure for Projects Rated as 'less than minimal risk'

See also Flowchart 2

Ethics documents for all projects to be submitted to supervisor ahead of agreed supervisor deadline for Year 3 and MSci projects and at least two weeks ahead of the module deadline for MSc projects (see relevant module outlines). Those rated as less than minimal risk by two staff members, in addition to the supervising staff member, can be signed by these staff members on Ethics Review and Approval Form (Form 1).

The researcher must ensure that the Senior Clerical Officer receives the signed Ethics Review and Approval Form (Form 1), stapled together with accompanying documents (information sheet, consent form, questionnaire pack etc), so that details can be entered onto the School's Research/Ethics Register.

Flowchart 2 – Procedure for Projects Rated as 'less than minimal risk'



Procedure for Projects Rated as 'more than minimal risk'

Projects rated as having 'more than minimal risk' needs to be assessed by the Ethics Committee.

To do this the committee will require:

- The protocol
- The information sheet
- The informed consent (Form 2 or 3)
- Completed ethics review and approval form (Form 1)
- Any questionnaires
- Any other pertinent information

All of these documents should therefore be submitted to the chair of the ethics committee, Dr Anthony Blanchfield, via e-mail in advance of your module deadline, as indicated in your module handbook.

NOTE: ANY PROJECTS TO BE PERFORMED DIRECTLY IN CONJUNCTION WITH A LARGER RESEARCH PROJECT THAT ALREADY HAS ETHICAL APPROVAL CAN BE SIGNED OFF BY THE PROJECT SUPERVISOR.

THIS CAN BE DONE BY DISCLOSING ON FORM 1 THAT THE PROJECT ALREADY HAS ETHICAL APPROVAL AND BY PROVIDING THE EXISTING SSHES ETHICS NUMBER FOR THAT APPROVED PROJECT

Process

The project will initially be assessed by the Chair or deputy.

If it is felt there are no ethical issues or undue risks associated with the project, the Chair, or deputy, may use their executive authority to approve the study without consulting the other members of the Ethics Committee.

If there are ethical issues or undue risk or other concerns, the project will be assessed by the Ethics Committee. This may be done informally (usually electronically) but if the difficulties are not simply resolved the Committee will meet to discuss the project. The researchers may be asked to supply further information or may be requested to attend the meeting in person.

If it is not possible to resolve the difficulties, or the project involves human tissue, clinical procedures, NHS staff or patients, or exposure to radiation the project is considered by the Betsi Cadwaladr University Health Board - West Ethics Committee. Other issues may be referred the University Ethics Committee.

Once approval has been granted the Chair will sign Form 1 and if there are any special strictures confirm these in writing to the researcher.

The researcher will then register the project with the Senior Clerical Officer.

If the researcher is unhappy with the outcome of the deliberations of the SSHES Ethics Committee, he/she may appeal to the University's Ethics Committee using the Appeal Process which is set out in Appendix 8.

This must be done in writing within 14 days of the receipt of the written opinion of the SSHES Committee.

Flowchart 3 – Procedure for Projects Rated as 'more than minimal risk'

Procedures for Projects Involving People Under 18

See Page 7 for definitions.

The procedure for obtaining informed consent for children, minors and dependent or vulnerable people is described on Page 15. Form 3 is to be used.

In the interests of child protection, in most circumstances the law requires researchers working with children or vulnerable people to undergo a check by the Disclosure and Barring Service (DBS), (as set out in Appendix 6).

Procedure for Projects Involving NHS Patients or Medical Treatment

All projects involving storage of human tissues or cells, clinical procedures, NHS patients or staff, medical treatment or exposure to radiation must be submitted to the Betsi Cadwaladr University Health Board - West Ethics Committee as well as to the SSHES Ethics Committee. The NHS procedure should be traversed first. When the project has been approved, the SSHES Ethics Committee should be informed and the project registered on the SSHES Research Register. The NHS procedure is more demanding than the SSHES process and involves a lot more form filling. This is done on line at: <https://www.myresearchproject.org.uk/>

At Ysbyty Gwynedd the process is overseen by Dr Rossela O Roberts, Clinical Governance Officer (Research and Development Manager/ Ethics Co-ordinator) who is very helpful and welcomes early enquiries.

E-mail: rosella.roberts@nww-tr.wales.nhs.uk

Details of the NHS process can be found in Appendix 7 – Guidance for Applicants.

The Betsi Cadwaladr University Health Board – West Ethics Committee assesses projects at its monthly meetings. Researchers are usually expected to attend these meetings to present their project and answer questions from the committee. All projects are also assessed by The Trust Research Governance Committee/Internal Review Panel for Research and Development.

If there are any difficulties **Dr Anthony Blanchfield** will be able to help.

In the course of the NHS Ethics Committee process the researcher will be required to find a 'sponsor' for the study. This will usually be the NHS Trust but may be the University. If it is the University, the Head of School (or deputy) will sign the form for you.

Procedure for Gaining Ethics Approval for Staff Research, PhD and MPhil Projects

It is the responsibility of the individual members of staff and PhD and MPhil students to obtain ethics approval for all research which they carry out within the School. Even if approval has been gained from an external Ethics Committee, the project still needs to be considered by the SSHES Ethics Committee (see below).

The SSHES research ethics committee has a monthly submission window that opens on the final Wednesday of every month and closes at midnight on the first Wednesday (inclusive) of the new month. All documentation should be sent to the chair of the SSHES Research Ethics Committee (Anthony Blanchfield), via e-mail, during this window for that application to be reviewed at the monthly SSHES research ethics committee meeting. This monthly meeting will take place on the third Wednesday of every month. Responses to each applicant can be expected by the fourth Wednesday of every month.

On receipt of this response, should your application require minor responses you can re-submit this at any point and it can be reviewed via executive action by the chair or the deputy chair.

Should your application contain substantial ethical concerns that have not been addressed in the original application, it will require amendments and possibly a re-submission to be re-reviewed in the next SSHES research ethics committee meeting. If this is the case, your application with amendments must be resubmitted by midnight on the second Wednesday of the month after your received your response.

For all applications that require a response, you should reply to each request of the ethics committee via track changes in your application so as it is evident how you have addressed each requirement. On your resubmission, you should not delete any of the requests by the ethics committee. You should also not delete the original text in your documents after changes to it.

Should you add anything to your document, that was not requested by the SSHES research ethics committee, you should insert a comment directly acknowledging this change with a clear explanation about why this change has been made. In such circumstances, the original text accompanying this change should not be deleted by yourself prior to resubmission.

All responses should be sent by e-mail to the chair of the research ethics committee, Anthony Blanchfield using the SHES Ethics e-mail address below:

Shesethics@bangor.ac.uk

Once the application has received approval from the SSHES research ethics committee, the staff member or student is responsible for providing the Senior Clerical Officer with a copy of the completed Ethics Review and Approval Form

(Form 1) along with all other relevant documents (participant information sheet, consent form, questionnaire pack, and a protocol where applicable). An external ethics Committee's letter of approval (if applicable) may also be required where an external body has reviewed the application. The project can then be registered onto the School's Research/Ethics Register. One signed copy of all of these documents should also be retained by the researchers.

SSHES Research/Ethics Register

Once Ethics approval has been obtained, all projects with the names of the investigators will be entered on the School's Research/Ethics Register. This will enable external agencies to audit the research going on in the School and to ensure that all research has been through the ethics approval process.

Registration of the project on the SSHES Research Register means that the project will be covered for insurance purposes. Insurance cover or indemnification cannot be guaranteed for projects which are not so registered.

The Senior Clerical Officer manages the register.

NB – It is researcher's responsibility to ensure that their projects are registered.

The researcher of projects approved by the SSHES Ethics Committee will supply the Senior Clerical Officer with a copy of the completed Ethics Review and Approval Form (Form 1) so the project can be entered on the Research/Ethics Register.

When a project has been approved by an external Ethics Committee the researcher is responsible for ensuring the project is submitted to the SSHES Ethics Committee and then providing the Senior Clerical Officer with a copy of the Ethics Committee's letter of approval so that the project can be registered onto the School's Research/Ethics Register.

Insurance Cover

Employer's Liability Insurance, Public and Product's Liability Insurance, and Professional Indemnity Insurance are reviewed and renewed annually by the University's Finance Office. Some funding bodies require information about insurance cover. The following letters usually sufficient in providing information to funding bodies:

- Professional Indemnity (*copy available from Insurance Officer in the Finance Office*)
- Liability Cover (*copy available from the Insurance Officer in the Finance Office*)

If something more is required, these matters are dealt with by:

Mr Chris Benson
Insurance Officer
Finance Office
Telephone: 01248 382199
E-mail: c.benson@bangor.ac.uk

Changes to a Research Plan

The Committee's approval of a research project covers only the procedures outlined by the applicant in the original application. Any changes in the procedures affecting interactions with human participants should first be sent to the chair of the research ethics committee, Anthony Blanchfield, via e-mail (sheethics@bangor.ac.uk). Changes that involve the addition or modification of procedures that are greater than minimal risk, or supplement dosages, will require review by the research ethics committee at its next monthly meeting and should therefore be submitted during the SSHES research ethics submissions window. Minor changes can be approved via executive action of the chair. If it is unclear from the document whether the amendment(s) are to be regarded as significant or minor, the chair has the dispensation to make this decision.

Ethics Forms

Apart from the police screening form (Disclosure and Barring Service – DBS), all forms referred to in this document can be downloaded from the School's U:\ Drive or collected from the Senior Clerical Officer.

Details of the Disclosure and Barring Service checking process are described in Appendix 6.

Further Information, Questions, etc

Please contact the Chair of the Ethics Committee, Anthony Blanchfield (a.w.blanchfield@bangor.ac.uk), or any member of the Committee if you require further information or have any questions. Please contact the module leader for any questions regarding module procedures in the first instance.

It is far easier to address ethical issues at the start of a project rather than on the night before you are giving your verbal presentation.

The Committee sees giving advice on the ethical aspects of a study at the design stage as an important part of its function and would far prefer being involved at this stage than having to reject a study for ethical reasons which could possibly have been avoided.

Guidance forms for many ethical considerations can be found on the U:drive – see hyperlink below

[U:\College of Health & Behavioural Sciences\SSHES\Ethics\ETHICS Supporting documents](#)

Summary of Forms

Form/Title	Version
Form 1 – Ethics Review and Approval Form	Revised 22/6/16
Form 2 – Informed Consent to Participate in a Research Project of Experiment	Revised 05/08/15
Form 3 – Informed Consent for Minors and Dependent Populations by Parent, Guardian and/or Other Appropriate Authority to Participate in a Research Project of Experiment	Revised 05/08/15
Form 4 – Physiology Informed Consent and Medical Questionnaire	Revised 05/08/15
Form 5 – Pre-Study Questionnaire	Revised 05/08/15
Form 6 – Participant Feedback Form	Revised 05/08/15
SHES PAR-Q Form	New 22/6/16

FORM 1 – Ethics Review and Approval Form

Please complete all parts of this form.

Please attach consent and information/debriefing sheets to all applications

Type of project requiring approval (*tick one box only*)

- | | |
|--|--|
| <input type="checkbox"/> Staff project | <input type="checkbox"/> PhD project |
| <input type="checkbox"/> MSc project | <input type="checkbox"/> Undergraduate project |
| <input type="checkbox"/> Class demonstration | |

1	Title of project	
2	Name and e-mail address(es) of all researcher(s)	
3	Name and e-mail address of supervisor (for student research)	
4	Proposed starting date	
5	Proposed duration	
6	What is your research question?	

- 7 Briefly explain the aims and relevance of your proposed study. Also outline the methodology (1/2 page maximum; express yourself in lay terms i.e. so that it is understandable to a non-specialist in the area)

8 Briefly describe the subjects you are planning to use in your study (include age, gender, and special status, e.g. children, learning disabled, vulnerable people).

9 Describe how you are going to recruit your participants.

10 Where will the study take place, e.g. university, school, hospital, athletic club?

11 How much time will each subject be required to give up for your research project (including travelling time)?

12 Do you intend to pay participants for their participation?

YES NO

If yes, what form will the payment take?

13 What are the risks to participants (physical and/or psychological)? Please explain fully what the risks are, how you plan to mitigate these, and **justify their necessity**.

- 14 The following research activities are considered to involve more than minimal risk and, consequently, require ethical review by the SSHES Ethics Committee.

Does your research involve any of the activities?

		YES	NO
i	NHS patients either in hospital or general practice?		
ii	Vulnerable groups? e.g., children and young people (i.e. under 18 years), those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship.		
iii	Sensitive topics? e.g., participants' sexual behaviour, their ille.g.al or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status.		
iv	Groups where permission of a gatekeeper is normally required for initial access to members?		
v	Deception or activities which are conducted without participants' full and informed consent at the time the study is carried out? If yes, i) please outline the alternative methodological approaches to your problem that you have discarded. It is simply not enough to say that you cannot obtain the data without the use of deception. You must indicate that you have considered other methodological approaches and that these were not appropriate. ii) in your opinion could the deception cause distress in subjects?		

vi	Access to records of personal or confidential information, including genetic and other biological information, concerning identifiable individuals?		
vii	Activities which might induce longer term psychological stress, anxiety or humiliation?		
viii	Intrusive interventions? e.g., the administration of drugs or other substances, vigorous physical exercise in people deemed 'at risk' (see PAR-Q below), or exposure to extreme physical or psychological conditions which could be injurious.		

IF YOU HAVE ANSWERED **YES** TO ANY OF THESE ACTIVITIES (FOR v, THIS ALSO REQUIRES 'YES' FOR vii) THEN YOUR PROJECT MUST BE REFERRED TO THE ETHICS COMMITTEE

(See also NOTES – Insurance cover against Litigation)

15 How are you going to handle the requirement of confidentiality?

16 During your data collection will supervision or assistance be required (e.g. for experiments in the physiology laboratory)?

YES NO

If yes, how will supervision be arranged?

17 How will you obtain informed consent?

i) How will you inform the subject about what is going to happen to him/her?

ii) How will the subject give consent?

iii) Does the project involve children?

YES NO

If yes,

- Children under the age of 16, their own consent (where possible) and parental/guardian consent is required (this must be written consent).
- Individuals aged over 16 and under 18 years, only their own consent is legally necessary (this must be written consent), but parental/guardian consent is desirable.

iv) People belonging to vulnerable groups?

YES NO

If yes,

- Parental/guardian consent is required. If this would offend the dignity of the participant, exception may be made for participants over the age of 18.

18 Is parental/guardian consent required for your project?

YES NO

19 If your project requires you to have access to children under the age of 18, police screening needs to be carried out. This requires a Disclosure and Barring Service (DBS) Form to be completed (ask the SSHES School Manager for more information).

Does police screening need to be carried out?

YES NO

.....
Signature of applicant

.....
Print Name

.....
Date

ETHICS APPROVAL ACTION

Take into account the responses to this form with particular reference to the activities listed in Q14

This project already has approval under SSHES Ethics No. _____

(Contact Mark Chitty if you are unsure of the Ethics Register number; submit completed form to the General Office)

.....
Signature – supervising staff member Print Name Date

This project does NOT require referral to the Ethics Committee
(Submit completed form to the General Office)

.....
Signature – supervising staff member Print Name Date

.....
Signature of second staff member Print Name Date
(e.g. cross moderator for student projects)

.....
Signature of third staff member Print Name Date
(e.g. member of Ethics Committee)

This project requires referral to the Ethics Committee

Submit this form, the information sheet, the customised consent form (Form 2 or 3 as appropriate) and the protocol to the SSHES Ethics Committee for consideration and approval.

If approved, Ethics Committee Chair to sign below in addition to the supervising staff member.

.....
Signature – supervising staff member Print Name Date

.....
Signature granting approval by Print Name Date
Chair of Ethics Committee
(Dr Anthony Blanchfield)

This completed and signed form must be submitted to the General Office for registration on the SSHES Ethics Register before data collection may commence.

FORM 2 – Informed Consent to Participate in a Research Project or Experiment

1	Title of project	
2	Name and e-mail address(es) of all researcher(s)	

Please tick boxes:

- 1 I confirm that I have read and understand the Information Sheet dated for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2 (i) Patients:
I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason, without my medical care or legal rights being affected.
- (ii) Students:
I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason. If I do decide to withdraw I understand that it will have no influence on the marks I receive, the outcome of my period of study, or my standing with my supervisor or with other staff members of the School.
- (iii) General members of the public:
I understand that my participation is voluntary and that I am free to withdraw at any time without giving a reason.
- 3 I understand that I may register any complaint I might have about this experiment with Professor Tim Woodman, Head of School of Sport, Health and Exercise Sciences, and that I will be offered the opportunity of providing feedback on the experiment using the standard report forms.
- 4 I agree to take part in the above study.

Name of Participant

Signature Date

Name of Person taking consent.....

Signature Date

WHEN COMPLETED – ONE COPY TO PARTICIPANT, ONE COPY TO RESEARCHER FILE

FORM 3 – Informed Consent for Minors and Dependent Populations by Parent, Guardian and/or Other Appropriate Authority to Participate in a Research Project or Experiment

1	Title of project	
2	Name and e-mail address(es) of all researcher(s)	

I (name of parent/guardian) am the parent/guardian of
 (name of child/dependent participant)

Please tick boxes

- 1 I confirm that I have read and understand the Information Sheet dated for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.
- 2 I certify that I understand the procedures to be used and have fully explained them to the above named child/dependent.
- 3 I understand that my child's/dependent's participation is voluntary and that he/she is free to withdraw at any time without giving a reason, without his/her medical care or legal rights being affected.
- 4 I understand that I may register any complaint I might have about this experiment with the Head of the School of Sport, Health and Exercise Sciences, and that I will be offered the opportunity of providing feedback on the experiment using the standard report forms.
- 5 I agree to the above named child/dependent taking part in the above study.

Name of Parent/Guardian

Signature Date

Name of Person taking consent.....

Signature Date

WHEN COMPLETED – ONE COPY TO PARTICIPANT, ONE COPY TO RESEARCHER

FORM 4 - Physiology Informed Consent and Medical Questionnaire

Name of Participant

Age

Are you in good health? YES NO

If no, please explain

How would you describe your present level of activity?

Tick intensity level and indicate approximate duration.

Vigorous		Moderate		Low intensity	
----------	--	----------	--	---------------	--

Duration (minutes).....

How often?

< Once per month		2-3 times per week	
Once per month		4-5 times per week	
Once per week		> 5 times per week	

Have you suffered from a serious illness or accident? YES NO

If yes, please give particulars:

Do you suffer from allergies? YES NO

If yes, please give particulars:

Do you suffer, or have you ever suffered from:

	YES	NO		YES	NO
Asthma			Epilepsy		
Diabetes			High blood pressure		
Bronchitis					

Are you currently taking medication? YES NO

If yes, please give particulars:

Are you currently attending your GP for any condition or have you consulted your doctor in the last three months? YES NO

If yes, please give particulars:

Have you, or are you presently taking part in any other laboratory experiment? YES NO

PLEASE READ THE FOLLOWING CAREFULLY

Persons will be considered unfit to do the experimental exercise task if they:

- have a fever, cough or cold, or suffer from fainting spells or dizziness;
- have suspended training due to a joint or muscle injury;
- have a known history of medical disorders, i.e. high blood pressure, heart or lung disease;
- have had hyper/hypothermia, heat exhaustion, or any other heat or cold disorder;
- have anaphylactic shock symptoms to needles, probes or other medical-type equipment;
- have chronic or acute symptoms of gastrointestinal bacterial infections (e.g. Dysentery, Salmonella);
- have a history of infectious diseases (e.g. HIV, Hepatitis B); and if appropriate to the study design, have a known history of rectal bleeding, anal fissures, haemorrhoids, or any other condition of the rectum.

PLEASE COMPLETE AND SIGN THE DECLARATION BELOW

DECLARATION

I agree that I have none of the above conditions and I hereby volunteer to be a participant in experiments/investigations during the period of20.....

My replies to the above questions are correct to the best of my belief and I understand that they will be treated with the strictest confidence. The experimenter has explained to my satisfaction the purpose of the experiment and possible risks involved.

I understand that I may withdraw from the experiment at any time and that I am under no obligation to give reasons for withdrawal or to attend again for experimentation.

Furthermore, if I am a student, I am aware that taking part or not taking part in this experiment, will neither be detrimental to, or further, my position as a student.

I undertake to obey the laboratory/study regulations and the instructions of the experimenter regarding safety, subject only to my right to withdraw declared above.

Signature (*participant*) Date

Print name

Signature (*experimenter*) Date

Print name

FORM 5 – Pre-Study Questionnaire

Name of Participant

Researcher

Date

		YES	NO
1	Have you had any kind of illness or infection in the last two weeks?		
2	Are you taking any form of medication?		
3	Do you have any form of injury?		
4	Have you eaten in the last hour?		
5	Have you consumed any alcohol in the last 24 hours?		
6	Have you performed exhaustive exercise in the last 48 hours?		

IF THE ANSWER TO ANY OF THE ABOVE IS 'YES', THEN YOU MUST CONSULT A MEMBER OF STAFF BEFORE UNDERGOING ANY EXERCISE TEST.

Signature (participant) Date

FORM 6 – Participant Feedback Form

Completion of this form is **OPTIONAL** and is not a requirement of participation in the project. However, if you have served as a participant in a project and would care to comment on the procedures involved, you may complete the following form and send it to **Dr Anthony Blanchfield, Chair, School of Sport, Health and Exercise Sciences Research Ethics Committee, Bangor University, Bangor LL57 2PZ**. All information received will be treated in a strictly confidential manner.

Name of Researcher

Title of Project

I wish to comment on my involvement in the above project which took place:

on
(Date) (Time)

at.....
(Place)

Did you sign an Informed Consent Form before participating in the project?

YES NO

Were there significant deviations from the originally stated procedures?

YES NO

Comments:

Completion of this section is optional:

Name of Participant.....

Address.....

.....

Telephone (Work) (Home)

Experimental work in sport and exercise physiology relies on individuals volunteering to take part in experiments. We are most grateful for this and we try to achieve the highest standards in consideration of the welfare and safety of subjects. To help us maintain and enhance these standards we would be most grateful if you could spare a little time to answer the following questions:

- 1 Describe briefly the experiment you participated in
- 2 Were you asked to complete a medical questionnaire?
- 3 Were you asked to complete an informed consent form?
- 4 Do you feel you participated totally voluntarily? Did you feel any degree of obligation to the experimenter or your friends?
- 5 Did you feel that the experiment took place in a safe and healthy environment?
- 6 Did you receive clear and adequate information about the experiment before you started?
- 7 Was the experiment you were asked to do 'reasonable' (that is, the exercise wasn't unduly stressful; after the experiment you didn't suffer any lasting physical or psychological distress etc).
- 8 Any other comments?

Please send completed form to Dr Anthony Blanchfield, Chair, SSHES Ethics Committee c/o School of Sport, Health and Exercise Sciences, Bangor University, George Building, Bangor LL57 2PZ.

PAR-Q & YOU – A Questionnaire for People Aged 15 to 69

Regular physical activity is fun and healthy, and increasingly more people are starting to become more active every day. Being more active is very safe for most people. However, some people should check with their doctor before they start becoming much more physically active.

If you are planning to become much more physically active than you are now, start by answering the seven questions in the box below. If you are between the ages of 15 and 69, the PAR-Q will tell you if you should check with your doctor before you start. If you are over 69 years of age, and you are not used to being very active, check with your doctor.

Common sense is your best guide when you answer these questions. Please read the questions carefully and answer each one honestly: check YES or NO.

YES NO

1 Has your doctor ever said that you have a heart condition and that you should only do physical activity recommended by a doctor?

2 Do you feel pain in your chest when you do physical activity?

3 In the past month, have you had chest pain when you were not doing physical activity?

4 Do you lose your balance because of dizziness or do you ever lose consciousness?

5 Do you have a bone or joint problem (for example, back, knee or hip) that could be made worse by a change in your physical activity?

6 Is your doctor currently prescribing drugs (for example, water pills) for your blood pressure or heart condition?

7 Do you know of any other reason why you should not do physical activity?

If you answered



YES to one or more questions:

Talk with your doctor by phone or in person BEFORE you start becoming much more physically active or BEFORE you have a fitness appraisal. Tell your doctor about the PAR-Q and which questions you answered YES.

- You may be able to do any activity you want — as long as you start slowly and build up gradually. Or, you may need to restrict your activities to those which are safe for you. Talk with your doctor about the kinds of activities you wish to participate in and follow his/her



NO to all questions:

If you answered NO honestly to all PAR-Q questions, you can be reasonably sure that you can:

- start becoming much more physically active – begin slowly and build up gradually. This is the safest and easiest way to go.
- take part in a fitness appraisal – this is an excellent way to determine your basic fitness so that you can plan the best way for you to live actively. It is also highly recommended that you have your blood pressure evaluated. If your reading is over 144/94, talk with your doctor before you start becoming much more physically active.



DELAY BECOMING MUCH MORE ACTIVE:

- if you are not feeling well because of a temporary illness such as a cold or a fever – wait until you feel better; or
- if you are or may be pregnant – talk to your doctor before you start becoming more active.

PLEASE NOTE: If your health changes so that you then answer YES to any of the above questions, tell your fitness or health professional. Ask whether you should change your physical activity plan.

Informed Use of the PAR-Q:

The School of Sport, Health and Exercise Sciences has adapted this PAR-Q form for use of in conjunction with the Ethics Review and Approval form and informed consent for persons undertaking research which requires moderate to high-intensity physical activity. If you are in any doubt after completing this questionnaire, please consult your doctor prior to physical activity.

You are encouraged to keep a copy of the completed PAR-Q form.

NOTE: If the PAR-Q is being given to a person before he or she participates in a physical activity programme or a fitness appraisal, this section may be used for legal or administrative purposes.

"I have read, understood and completed this questionnaire. Any questions I had were answered to my full satisfaction."

NAME.....

SIGNATURE..... DATE.....

SIGNATURE OF PARENT or GUARDIAN (for participants under 18 or vulnerable adults)

..... DATE.....

SIGNATURE OF WITNESS

..... DATE.....

Note: This physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if your condition changes so that you would answer YES to any of the seven questions overleaf.

Acknowledgement – adapted from the PAR-Q form © Canadian Society for Exercise Physiology, 2002

List of Appendices

Title
Appendix 1 – Declaration of Helsinki
Appendix 2 – The British Association of Sport and Exercise Sciences (BASES) – Code of Conduct
Appendix 3 – British Psychological Society Code of Ethics and Conduct – sections: 3.3 Standard of Protection of Research Participants; 3.4 Standard of Debriefing of Research Participants.
Appendix 4 – American College of Sports Medicine – Policy Statement Regarding the Use of Human Subjects and Informed Consent
Appendix 5 – Advice on the preparation of Information Sheets for Research Purposes (Updated 12/3/09)
Appendix 6 – Disclosure and Barring Service (DBS) – Disclosure Procedures for Those Working with Children or Dependent People
Appendix 7 – North West Wales NHS Trust Research and Development Office – Guidance for Applicants
Appendix 8 – Procedure for those wishing to appeal against a decision of School Ethics Committee Appeals Procedure – Academic Ethics Committees

Appendix 1 – WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:

- 29th WMA General Assembly, Tokyo, Japan, October 1975
- 35th WMA General Assembly, Venice, Italy, October 1983
- 41st WMA General Assembly, Hong Kong, September 1989
- 48th WMA General Assembly, Somerset West, Republic of South Africa,
- October 1996 and the 52nd WMA General Assembly, Edinburgh, Scotland, October 2000

Note of Clarification on Paragraph 29 added by the WMA General Assembly, Washington 2002
Note of Clarification on Paragraph 30 added by the WMA General Assembly, Tokyo 2004

A INTRODUCTION

- 1 The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
- 2 It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.
- 3 The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."
- 4 Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
- 5 In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
- 6 The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the

best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.

- 7 In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
- 8 Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
- 9 Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B BASIC PRINCIPLES FOR ALL MEDICAL RESEARCH

- 10 It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
- 11 Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.
- 12 Appropriate caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.
- 13 The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance, and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials.

The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding funding,

sponsors, institutional affiliations, other potential conflicts of interest and incentives for subjects.

- 14 The research protocol should always contain a statement of the ethical considerations involved and should indicate that there is compliance with the principles enunciated in this Declaration.
- 15 Medical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given consent.
- 16 Every medical research project involving human subjects should be preceded by careful assessment of predictable risks and burdens in comparison with foreseeable benefits to the subject or to others. This does not preclude the participation of healthy volunteers in medical research. The design of all studies should be publicly available.
- 17 Physicians should abstain from engaging in research projects involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians should cease any investigation if the risks are found to outweigh the potential benefits or if there is conclusive proof of positive and beneficial results.
- 18 Medical research involving human subjects should only be conducted if the importance of the objective outweighs the inherent risks and burdens to the subject. This is especially important when the human subjects are healthy volunteers.
- 19 Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research.
- 20 The subjects must be volunteers and informed participants in the research project.
- 21 The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- 22 In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time

without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent, preferably in writing. If the consent cannot be obtained in writing, the non-written consent must be formally documented and witnessed.

- 23 When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.
- 24 For a research subject who is legally incompetent, physically or mentally incapable of giving consent or is a legally incompetent minor, the investigator must obtain informed consent from the legally authorized representative in accordance with applicable law. These groups should not be included in research unless the research is necessary to promote the health of the population represented and this research cannot instead be performed on legally competent persons.
- 25 When a subject deemed legally incompetent, such as a minor child, is able to give assent to decisions about participation in research, the investigator must obtain that assent in addition to the consent of the legally authorized representative.
- 26 Research on individuals from whom it is not possible to obtain consent, including proxy or advance consent, should be done only if the physical/mental condition that prevents obtaining informed consent is a necessary characteristic of the research population. The specific reasons for involving research subjects with a condition that renders them unable to give informed consent should be stated in the experimental protocol for consideration and approval of the review committee. The protocol should state that consent to remain in the research should be obtained as soon as possible from the individual or a legally authorized surrogate.
- 27 Both authors and publishers have ethical obligations. In publication of the results of research, the investigators are obliged to preserve the accuracy of the results. Negative as well as positive results should be published or otherwise publicly available. Sources of funding, institutional affiliations and any possible conflicts of interest should be declared in the publication. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.

C ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

- 28 The physician may combine medical research with medical care, only to the extent that the research is justified by its potential prophylactic, diagnostic or therapeutic value. When medical research is combined with medical care, additional standards apply to protect the patients who are research subjects.
- 29 The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists.¹
- 30 At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.²
- 31 The physician should fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a study must never interfere with the patient-physician relationship.
- 32 In the treatment of a patient, where proven prophylactic, diagnostic and therapeutic methods do not exist or have been ineffective, the physician, with informed consent from the patient, must be free to use unproven or new prophylactic, diagnostic and therapeutic measures, if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, these measures should be made the object of research, designed to evaluate their safety and efficacy. In all cases, new information should be recorded and, where appropriate, published. The other relevant guidelines of this Declaration should be followed.

Notes of Clarification

1 Note of clarification on paragraph 29 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that extreme care must be taken in making use of a placebo-controlled trial and that in general this methodology should only be used in the absence of existing proven therapy. However, a placebo-controlled trial may be ethically acceptable, even if proven therapy is available, under the following circumstances:

- Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method; or
- Where a prophylactic, diagnostic or therapeutic method is being investigated for a minor condition and the patients who receive placebo will not be subject to any additional risk of serious or irreversible harm.

All other provisions of the Declaration of Helsinki must be adhered to, especially the need for appropriate ethical and scientific review.

2 Note of clarification on paragraph 30 of the WMA Declaration of Helsinki

The WMA hereby reaffirms its position that it is necessary during the study planning process to identify post-trial access by study participants to prophylactic, diagnostic and therapeutic procedures identified as beneficial in the study or access to other appropriate care. Post-trial access arrangements or other care must be described in the study protocol so the ethical review committee may consider such arrangements during its review.

9.10.2004

Appendix 2 – BASES Code of Conduct

BASES, Beckett Park Campus, Leeds Metropolitan University,
Leeds LS6 3QS
Tel/Fax: 0113 2836162



THE BRITISH ASSOCIATION OF SPORT AND EXERCISE SCIENCES

CODE OF CONDUCT

1 Introduction

This code of conduct sets out the principles of conduct and ethics for the guidance of members of the British Association of Sport and Exercise Sciences (BASES) and its three constituent Divisions: Education and Professional Development; Physical Activity for Health; and Sport and Performance. All members of BASES are bound by the provisions of this code of conduct and each Division's own professional guidelines, which provide further detail in respect of experimental techniques, protocols and analysis procedures, the obtaining of medico-legal clearance and informed consent. BASES members are reminded that the aims of the Association are:

- a) the promotion of research in sport and exercise sciences;
- b) the encouragement of evidence-based practice in sport and exercise sciences;
- c) the distribution of knowledge in sport and exercise sciences;
- d) the development and maintenance of high professional standards for those involved in sport and exercise sciences;
- e) the representation of the interests of sport and exercise sciences nationally and internationally.

Throughout this Code of Conduct the word 'client(s)' includes all participants. In both, carrying out these aims and their working practices, BASES members must take into account the three following principles:

- f) all clients have the right to expect the highest standards of professionalism, consideration and respect;
- g) the pursuit of scientific knowledge requires that research and testing is carried out with utmost integrity;
- h) the law requires that working practices are safe and that the welfare of the client is paramount.

2 Structure

Members are reminded that the authority of BASES is vested in the Strategic Management Team, which alone has the power to review and recommend amendment to this code of conduct. Any questions arising from this code of conduct or its interpretation (apart from disciplinary matters for which see section 9) shall be referred at first by any member to the relevant Division Chair for a ruling. Such Chair may, at their discretion, refer such matter to the Strategic Management Team for final determination. Any member aggrieved

by the decision of a Division Chair may appeal to the Strategic Management Team for a ruling, whose decision shall be final.

3 Ethical Clearance

Ethical clearance must be obtained from an appropriate Local Ethics Committee or similar local body for non-routine work undertaken by members. Specific clearance must always be obtained before the imposition of any unusual or severe physical or psychological stress, the administration of any ergogenic aid, working with clients with disabilities, or the employment of biopsy or venipuncture. The list is not exhaustive and specific clearance is often required in other areas of work, such as with children, vulnerable adults or the sampling of capillary blood. If any member is in doubt as to whether ethical clearance is required, an assessment of risk should be carried out and if there is any remaining doubt reference should be made, in advance, to the local ethics committee or body.

4 Informed Consent and Confidentiality

a) Informed Consent

No member may undertake any work without first having the informed consent of all participating clients. Informed consent is the knowing consent of a client (or legally authorised representative in the case of the child) who is in a position to exercise free power of choice without any undue inducement or element of force, fraud, deceit or coercion.

In most cases, informed consent may be obtained by having the client read and sign a document setting out all of the information relevant to the proposed investigation or test. This would normally include a description of the investigation and its objectives, the procedures to be followed, an outline of the risks and benefits, an offer to answer any queries, an instruction that the client is free to withdraw at any point without prejudice, together with an explanation concerning confidentiality.

In some cases (e.g., simple field tests), informed consent may be obtained verbally but in every such case members must make an appropriate written record confirming that informed consent had been obtained. Where a full explanation to a client may adversely affect the work, members must obtain prior local ethics committee consent to provide a more general outline of the aims of the investigation and the committee may set out the extent of the information to be given at its discretion.

b) Confidentiality

It is of paramount importance that all BASES members must preserve the confidentiality of the information acquired in their work which must not be devolved without prior written consent of a client. All clients must be informed that they have a right to a copy of such information relating to them and all members must supply a copy if so requested. It is deemed to be good practice to supply copies in any event, as a matter of course.

Data Protection and Responsibility

- a) Storage and use of individually identifiable data must be in accordance with the provisions of the Data Protection Act 1998.
- b) The obtaining of data and its presentation/publication must be unbiased and responsible. Validity, objectivity and reliability are key principles and caution should be exercised with the interpretation and explanation of test results.
- c) Members should seek to maximise the accessibility of research findings and, wherever appropriate, publish them in the interest of both science, and sport and exercise.
- d) Publication of data must not disclose the identity of any individual client unless the prior written consent of the individual is obtained.

5 Competence

- a) Members must recognise their limitations in qualifications, experience, expertise and competence and must operate within these limits, restricting the interpretation of results to those which they are qualified to give and in employing any equipment and techniques which they are qualified to use.
- b) Any matter whose essence appears to lie within another specialist field such as medicine or physiotherapy, or another discipline within BASES, must be referred to an appropriate professional within such a field.
- c) Members must not misrepresent their qualifications, experience or expertise in any way or exaggerate or mislead clients in respect of the effectiveness of any techniques they undertake.
- d) Professional members should seek to become accredited where and when appropriate.
- e) All members must be knowledgeable in respect of contemporary research and practice.

6 Professional and Personal Conduct

- a) Members paramount concern is the well-being of their clients.
- b) Members must conduct themselves in such a way that brings credit to their specialist areas.
- c) Members must not practise or work when they are not fit to operate effectively and professionally.
- d) Members must not exploit relationships with clients for personal gain or gratification.

- e) Members must not in any way jeopardise the safety or interests of clients.
- f) Members must be totally unbiased and objective in their practices and actions.
- g) Members must ensure, where appropriate, the highest standards of safety and working practices and research both in respect of work undertaken by members themselves or by others under their supervision.
- h) Members must respond, with all due expedition, to any enquiry from any client or any other member of BASES or any committee of BASES.
- i) Members must ensure that suitable insurance indemnity cover is in place for all areas of work that they undertake.
- j) Members must not do any act or thing, or omit to do any act or thing, which in any way brings, or is likely to bring, BASES into disrepute.

7 Officers

All officers of BASES and the individual Divisions must:

- a) act with strict impartiality with respect of any matter referred to them for consideration as officers;,,
- b) use their best endeavours to make the best use of all resources available to
- c) BASES in the interests of BASES and its members;
- d) make a prior declaration in respect of any matter in which they have direct or indirect personal interest;
- e) not take part in any part of or vote on any matter in which they have a direct or indirect personal interest.

8 Disciplinary Procedures

- a) Any person (whether or not a member) may make a complaint that a member has failed to comply with this code of conduct. Members are under an obligation to report all instances of breaches of this code.
- b) Such complaint shall be made in writing to the Honorary Secretary of BASES.
- c) Upon receiving a complaint, the Honorary Secretary must investigate it as soon as possible unless the complaint is anonymous in which case the Secretary has the discretion as to whether to investigate it or not. The Honorary Secretary shall investigate any complaint impartially and with the assistance of a salaried member of the BASES staff or other nominated officer.
- d) The member shall receive full written details of the complaint against them.
- e) The member shall respond in writing within 28 days of receiving details of the complaint.
- f) The Honorary Secretary shall cause all such relevant enquiries to be made as the Honorary Secretary considers necessary to ascertain the validity or otherwise of the complaint and, as soon as possible

- thereafter, the Honorary Secretary shall refer the matter to a disciplinary tribunal.
- g) The disciplinary tribunal shall comprise the Chair of BASES, Division Chair of the member's Division and one other Division Chair and a BASES legal representative if deemed necessary.
 - h) The disciplinary tribunal shall meet as soon as conveniently possible to consider the complaint and will give reasonable notice to the member of the time, date and place of disciplinary tribunals meeting.
 - i) The member shall be entitled to attend the tribunal in person (with a representative if they so wish who must be identified 14 days before the tribunal meets) and shall be entitled to a copy of all documentation that the tribunal is considering.
 - j) The tribunal may call any person to give information to it and the member shall be entitled to ask any relevant questions of such person and shall be entitled to address the tribunal. Subject to this, the disciplinary tribunal shall have the power to decide the form and nature of any hearing but any such procedure must be fair and reasonable to all parties.
 - k) At the conclusion of the hearing, the disciplinary tribunal must adjudicate on the complaint and decision may be reached by a majority.
 - l) **Appendix 2**
 - m) In the event that the complaint is upheld the disciplinary tribunal shall have full discretion to impose any of the following penalties on any member:
 - n) a written caution as to future behaviour;
 - o) a fine;
 - p) suspension from membership for a fixed period;
 - q) expulsion from membership.
 - r) Prior to the imposition of suspension or expulsion a member must be provided with the opportunity to make a written or personal presentation to the tribunal.
 - s) Written notice of any penalty imposed shall be given to the member and a copy may be circulated to any other member.
 - t) On being presented with any new relevant evidence the tribunal has the discretionary power to review any complaint and may, on any such review, review not only its prior decision but also any penalty imposed whether by reducing, increasing or cancelling the same.
 - u) If any member is aggrieved by the decision of the disciplinary tribunal, he or she may, within fourteen days of receiving the written decision of the disciplinary tribunal, appeal the decision to the Strategic Management Team who shall have full power to consider the matter afresh, excluding the original tribunal members, together with full power to reduce, increase, cancel or confirm any penalty imposed.

Appendix 3 – British Psychological Society Code of Ethics and Conduct

The Code of Ethics and Conduct

The British Psychological Society, March 2006

3.3 Standard of Protection of Research Participants

Psychologists should:

- i. Consider all research from the standpoint of research participants, for the purpose of eliminating potential risks to psychological well-being, physical health, personal values, or dignity.
- ii. Undertake such consideration with due concern for the potential effects of, for example, age, disability, education, ethnicity, gender, language, national origin, race, religion, marital or family status, or sexual orientation, seeking consultation as needed from those knowledgeable about such effects.
- iii. Ask research participants from the first contact about individual factors that might reasonably lead to risk of harm, and inform research participants of any action they should take to minimise such risks.
- iv. Refrain from using financial compensation or other inducements for research participants to risk harm beyond that which they face in their normal lifestyles.
- v. Obtain the considered and non-subjective 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.
- vi. Inform research participants from the first contact that their right to withdraw at any time is not affected by the receipt or offer of any financial compensation or other inducements for participation.
- vii. Inform research participants from the first contact that they may decline to answer any questions put to them, while conveying as well that this may lead to termination of their participation, particularly when safety issues are implicated.
- viii. 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 well-being.

- ix. Exercise particular caution when responding to requests for advice from research participants concerning psychological or other issues, and offer to make a referral for assistance if the inquiry appears to involve issues sufficiently serious to warrant professional services.

And

- x. When conducting research involving animals:
 - a) observe the highest standards of animal welfare, including reduction to the minimum of any pain, suffering, fear, distress, frustration, boredom, or lasting harm;

And

- b) avoid the infliction of any of these conditions which cannot be strictly justified, in adherence to the Society's published *Guidelines for Psychologists Working with Animals*.

3.4 Standard of Debriefing of Research Participants

Psychologists 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 as needed.

And

Take particular care when discussing outcomes with research participants, as seemingly evaluative statements may carry unintended weight.

Appendix 4 – American College of Sports Medicine – Policy Statement Regarding the Use of Human Subjects and Informed Consent

American College of Sports Medicine

Medicine and Science in Sports and Exercise: Volume 28(10) October 1996p
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POLICY STATEMENT REGARDING THE USE OF HUMAN SUBJECTS AND INFORMED CONSENT

By law, any experimental subject or clinical patient who is exposed to possible physical, psychological, or social injury must give informed consent prior to participating in a proposed project. Informed consent can be defined as the knowing consent of an individual or his legally authorized representative so situated as to be able to exercise free power of choice without undue inducement or any element of force, fraud, deceit, duress, or other form of constraint or coercion.

The Editorial Board of MEDICINE AND SCIENCE IN SPORTS AND EXERCISE

requires that all appropriate steps be taken in obtaining the informed consent of any and all human subjects employed by investigators submitting manuscripts for review and possible publication. In most cases, informed consent should be obtained by having the subject read a document (an Informed Consent Form) presenting all information pertinent to the investigation or project and affixing a signature indicating that the document has been read and consent given to participation under the conditions described therein. The document should be written so that it is easily understood by the subjects and provided in a language in which the subjects are fluent.

Investigators are requested to consider the following items for inclusion in an Informed Consent Form as appropriate to the particular project:

1. A general statement of the background of the project and the project objectives.
2. A fair explanation of the procedures to be followed and their purposes, identification of any procedures which are experimental, and description of any and all risks attendant to the procedures.
3. A description of any benefits to be reasonably expected and, in the case of treatment, disclosure of any appropriate alternative procedures that might be advantageous to the subject.
4. An offer to answer any queries of the subject concerning procedures or other aspects of the project.

5. An instruction that the subject is free to withdraw consent and to discontinue participation in the project or activity at any time without prejudice to the subject.
6. An instruction that, in the case of questionnaires and interviews, the subject is free to deny answer to specific items or questions.
7. An instruction that, if services or treatment are involved in the setting or context of the project, they will be neither enhanced nor diminished as a result of the subject's decision to volunteer or not to volunteer participation in the project.
8. An explanation of the procedures to be taken to insure the confidentiality of the data and information to be derived from the subject. If subjects are to be identified by name in the manuscript, permission for same should be obtained in the Informed Consent Form or obtained in writing at a later date.

If the subject is to be videotaped or photographed in any manner, this must be disclosed in the Informed Consent Form. The subject must be advised as to who will have custody of such videotapes or photographs, who will have access to the tapes or photographs, how the tapes or photographs are to be used, and what will be done with them when the study is completed.

The informed consent document must not contain any exculpatory language or any other waiver of legal rights releasing, or appearing to release, an investigator, project director, or institution from liability. At the bottom of the form, provision should be made for the signature of the subject (and/or a legally authorized representative) and the date. It is generally advisable to precede this with a statement to the effect that the subject and/or representative have read the statement and understand it. In the case of minors, one or both parents should sign (as appropriate). For minors of sufficient maturity, signatures should be obtained from the subject and the parent(s).

The Editorial Board endorses the Declaration of Helsinki of the World Medical Association as regards the conduct of clinical research. Physicians are expected to comply with the principles set forth in this declaration when research involves the use of patients. In the case of psychological research, investigators will be expected to comply with the principles established by the American Psychological Association. These principles are presented in the publication, *Ethical Principles in the Conduct of Research with Human Participants* (American Psychological Association, Washington, D.C., 1982).

It will not be necessary for an author to describe in the manuscript the specific steps that were taken to obtain informed consent, to insure confidentiality of results, or to protect the privacy rights of participating subjects. It will be satisfactory for the author to indicate that, informed consent was obtained from the subject, or by similar wording. It will be understood by the editors that

such a statement indicates the author's guarantee of compliance with the directives presented above.

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Appendix 5 – Advice on the Preparation of Information Sheets for Research Purposes

The information sheet should be printed on SSHES headed paper. The following headings are suggested:

1 Study Title

Is the title self-explanatory to a lay person? If not, a simplified title should be included.

2 Invitation paragraph

This should explain that the participant is being asked to take part in a research project. The following is a suggested way of doing this:

“You are being invited to take part in a research study. Before you agree to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. If you wish, discuss it with friends and relatives. If you are concerned you may like to discuss it with your GP. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part, or not”.

3 What is the background of the study?

The background and the aims of the study should be described.

4 Do I have to take part?

You should explain that participation in the research is entirely voluntary. You could use the following paragraph:

“It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are free to withdraw at any time and without giving a reason. This will not affect the marks you receive, the outcome of your period of study at SSHES or your standing with your supervisor, other staff members or with the School”.

Note: In studies where questionnaires and interviews are used it should be stated that the participant is free not to answer specific items or questions.

5 What will happen to me if I take part?

You should explain in simple English what exactly will happen to the participant. Will it involve blood tests, nude weighing, rectal probes, DEXA scanning or other invasive procedures? Does it involve exercise, if so what type, how long and under what circumstances? How long it will take, how

many times will the participant need to visit? What are the participants' responsibilities? Set down clearly what you expect of them.

6 What do I have to do?

Are there lifestyle restrictions? Will the participant have to fast, to abstain from alcohol, coffee, tobacco etc? Can the participant drive, play sport or continue training?

7 What are the possible disadvantages and risks of taking part?

The disadvantages and risks of taking part should be clearly described, as should everything which has been done to minimise them. The disadvantages and risks of invasive procedures such as blood tests, rectal probes and DEXA scanning should be specifically described. How much time will the participant have to give up?

8 What are the possible benefits of taking part?

It is important not to exaggerate the possible benefits to the participant, because this could be seen as coercive. However, there may well be benefits to the individual, for example by allowing access to special training or assessments. As well as benefits to the individual participant, the discovery of new information can benefit other individuals, groups, or people with illnesses and/or disabilities and mankind in general. There might well be benefits for sportspeople generally or participants in particular sports which could be mentioned, as could the downstream effects of what the study might discover.

9 Confidentiality

The following paragraph is suggested to cover confidentiality:

"All information which is collected about you during the course of the research will be kept strictly confidential. Any information which leaves the School will have your name and address removed so that you cannot be recognised from it. It will not be possible to identify you in any report or publication of the study".

Note: If a participant is to be videotaped, audio taped or photographed in any manner, this must be disclosed in the information sheet. The participant must be advised as to who will have custody of such videotapes or photographs, how the tapes or photographs are to be used, and what will be done with them when the study is over.

10 Who is organising or funding the research? (if applicable)

11 Who has reviewed the study?

You should mention that the study has been reviewed as per the SSHES ethics process and if there are more than minimal risks (see Page 18) they

should be spelt out in this section. If the study has been approved by another Ethics Committee it should be stated here

12 Feedback on Conduct of Research

SSHES is always keen to hear the views of research participants about their experience. Form 6 in the Guidelines Handbook allows participants to feedback. It is suggested that the Information Sheet includes the following paragraph:

"SSHES is always keen to hear the views of research participants about their experience. If you would like to feedback, please ask your researcher to provide you with Form 6 – Participant Feedback Form – from the Ethics Guidelines Handbook. Completion of this form is optional. The completed form should be returned to Prof. Andrew Lemmey, Chair, SSHES Ethics Committee, SSHES, Bangor University, Bangor LL57 2PZ. All information will be treated in a strictly confidential manner."

13 Any Questions?

"Please ask us if you have any questions. You should not sign the form consenting to take part in the study if you still have unanswered questions or any doubts".

14 Names, addresses, email and contact phone numbers of the researchers must be clearly displayed.

Appendix 6 - Disclosure & Barring Service (DBS) Procedure for Research Involving Children

All research involving children or minors (i.e. people under 18) requires DBS clearance.

Allow plenty of time to arrange this.

The procedure is as follows:

- Obtain a DBS Application Form (and Applicants' Guide) from the School Manager;
- Complete the form;
- Take the completed form to the School Manager with cash or a cheque for the fee of £44.00 and the required documents which are listed on the DBS Application Form. Copies of the documents are retained for 6 months by the School Manager. The completed form will be sent off for you;
- The applicant will receive a DBS certificate and this must be shown to the School Manager who will then record the certificate number and date when seen.

***NB** – Cheques should be made payable to 'Bangor University'.

Appendix 7 – Betsi Cadwaladr University Health Board – West Research and Development Office, Guidance for Applicants



The process of getting a research project approved involves applying for:

- 1 Trust management approval – granted by Trust Research Governance Committee / Internal Review Panel
- 2 Ethical approval – North West Wales Research Ethics Committee

Both application forms can be found at <https://www.myresearchproject.org.uk> – the web based integrated application system through which you can apply for all permissions needed for research in the UK.

All research activity must be registered with the Research Office and approved on behalf of the Trust by the Research Governance Committee (TRGC). Unregistered and unapproved research will not be supported or indemnified.

Researchers are notified that every research project involving human participants in their capacity of NHS patients or staff, or conducted on human participants on NHS premises, must have ethical approval before commencing.

Below you will find a summary of the documents required for submission to each committee.

Included in the information pack are details of both Committees, with submission and meeting dates. Following this you will find detailed guidance on how to produce all documents required for submission.

Trust Management approval

meets on the first Thursday of each month.

The deadline for submissions is ten working days before the meeting.

You will need to submit the following documents:

- 1 Applications for RandD approval must be made using the:

a) NHS RandD Application Form

You can find the online application form at <https://www.myresearchproject.org.uk> and

- The **Site Specific Information form** from the same website and
- The **NHS RandD supplementary information form** (finance section compulsory and additional ones if applicable i.e. pharmacy, ionising radiation, support services, etc) not on the website but Trust specific and available electronically from the RandD office.

Please ensure that all the relevant signatures are in place on the form, including the Investigator, Sponsor, and authorisations from: Clinical Director and DGM, Data Protection Officer (compulsory), Clinical Supervisor, Academic Supervisor, Support Services, Caldicott Guardian and IRMER practitioner, (where applicable).

- 2 **The XML file** sent electronically²
- 3 **Research Proposal** (protocol) and all supporting documents as appropriate (lay summary, Investigator's Brochure or Summary of Product Characteristics, copies of questionnaires, treatment schedule, interview schedule, etc.)
- 4 **Participant Information Sheet** and **Consent Form** - Welsh language version included.
- 5 Letter to the Consultant/GP (if appropriate).
- 6 **Investigators' CV** and where relevant the academic supervisor's CV.
- 7 Letter from the Sponsor, including indemnity documents.
- 8 Any other supporting document you might consider helpful (pharmacy haematology etc. agreements)

All documents must have a version number and date

² To do this click on the 'Manage' tab in your main application, then on 'Export project data into xml'. Save this file DO NOT OPEN and e-mail a copy to the REC office.

The application must be accompanied by an explanatory cover letter to the Chairman (Dr. Keith Griffiths).

Both paper and electronic copies of all documents listed above must be submitted for Trust Approval.

Note: If, after the meeting, the Committee requested you to supply more information or amend specific parts of your project, please submit the information by the next meeting, following the same deadline rules.

Ethical Approval

The Betsi Cadwaladr University Health Board - West Research Ethics Committee

meets every third Thursday of the month.

The application deadline is ten working days before the meeting.

- 1 Applications for ethical review by an NHS REC must be made using the **NHS REC Application Form**.

You can find the online application form at
<https://www.myresearchproject.org.uk>

You can find guidance on completing the form and supporting documentation on the help section of the website. Supplementary information on the National Research Ethics System is available from:
<http://www.nres.npsa.nhs.uk>

Please contact the REC prior to starting the process to obtain a reference number for your project, which must be inserted in the form.

Once you have completed the form you must 'Print for Submission' this action locks the form ensuring that no further changes can be made once submitted to the Committee.³ You and your sponsor (and academic supervisor if applicable) must sign this form and submit it with the documents detailed below.

- 2 **The documents listed on the previous page** (pt.2 to 8) must also be submitted to the Ethics Committee.

Please bear in mind that the REC will need the signed printed application and all documents before it can acknowledge its receipt as a valid application.

³ To do this, go into your project, click on 'NHS REC Form' under Project forms (this appears on the Navigation Page of your project). Click on the 'Submission' tag, then 'Print for Submission'. This will print a copy of the form with a lock code on the bottom right hand corner.

The application must be accompanied by the completed checklist and an explanatory cover letter to the Chairman, Mr D. Owen.

The Ethics Committee will acknowledge the receipt of your application, it will be allocated to the REC meeting, and you will be invited to speak to your submission.

If at any stage of the application process you need assistance or additional information please don't hesitate to contact:

Dr. Rossela O. Roberts
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Ethics Co-Ordinator)
Clinical Academic Office
Betsi Cadwaladr University Health Board - West NHS Trust
Ysbyty Gwynedd
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Appendix 8 – Procedure for those wishing to appeal against a decision of School Ethics Committee

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Appeals Procedure – Academic Ethics Committees

Applicable to all members of staff and students who have submitted research for consideration by one of the University's Academic Ethics Committees:

1. The following may appeal under this procedure against the decision of an Academic Ethics Committee (AEC)⁴ not to grant ethical approval to a research proposal or against the decision to grant ethical approval subject only to certain conditions:
 - a member of staff at Bangor University;
 - a student at Bangor University;
 - any persons not employed by Bangor University but with permission to carry out research at the University.
2. The University will only consider appeals which are based on one or more of the following grounds:
 - 2.1 Defects or irregularities in the procedures or conduct of the AEC or in advice relating thereto which are of such a nature as to cause reasonable doubt whether members of the AEC would have reached the same decision had they not occurred.
 - 2.2 Evidence of prejudice or of bias or of inadequate assessment on the part of one or more of the members of the AEC.
 - 2.3 Where advice given by the advisor(s) assigned by the University in relation to presenting the proposal to the relevant AEC was inadequate and there were exceptional reasons why the researcher failed to report this to the Chair of the relevant AEC prior to the point at which the AEC came to its decision.
3. Any appeal must be sent, in full and in writing to the Chair of the University Ethics Committee, Bangor University, c/o Registrar's Office, College Road, Bangor, Gwynedd, LL57 2DG and must reach him/her not later than **two months** after the date of the decision of the AEC. Receipt of the application for appeal should normally be acknowledged within three working days and the appellant should be provided with a written progress report within 25 working days.
4. If it is decided by the Chair of the University Ethics Committee or his/her nominee that there is a *prima facie* case to be considered, it will be referred to an Ethics Appeal Board consisting of three persons chosen from amongst the members of the University Ethics Committee. The

⁴ As defined by the University's Research Ethics Framework which can be accessed from: <http://www.bangor.ac.uk/ar/ro/recordsmanagement/REF.php.en>

Board will be chaired by the Chair of the University Ethics Committee or his/her nominee. The Board must normally consider the appeal within three months of receipt of the application.

5. Where a case is referred to an Ethics Appeal Board, the Board must identify the grounds for the appeal, and must base its decision on the evidence contained in the appellant's submission, the testimony of the Chair of the relevant AEC, the evidence of a representative of the School concerned, and any further evidence which it considers relevant.
6. An appellant will normally be offered a personal hearing and be informed of the time and date of the hearing. The appellant may be accompanied, but not represented, by a member of the academic, welfare or advisory staff of the University, a student or officer of the Students' Union or a member of a trades union.
7. The Ethics Appeal Board will have discretion to declare inadmissible any matter raised at the hearing that it deems not to be directly related to the contents of the appeal, with the Chair able to exercise a casting vote where necessary.
8. An Ethics Appeal Board is empowered to take either of the following decisions:
 - 8.1 to reject the appeal;
 - 8.2 to uphold the appeal.
9. If an appeal is upheld, the Ethics Appeal Board may also adopt one of the following courses of action:
 - 9.1 To recommend to the relevant AEC that, for the reasons stated, the original, or a properly constituted, AEC should reconsider the decision of the relevant meeting of the AEC.
 - 9.2 To recommend that an entirely newly constituted AEC should reconsider the decision of the previous Committee.
10. The decision of an Ethics Appeal Board is final.
11. In the case of 8 or 9 above, the Chair of the University's Ethics Committee or the person nominated from the Committee to act on his/her behalf in relation to the appeal will arrange for the decision and recommendations of the Board to be implemented.
12. Any decisions of an Ethics Appeal Board should be reported, as a reserved item, to the University Ethics Committee at the meeting following the decision of the Board.

Version 1: Approved by the University Ethics Committee 9 April 2008