Applying to the SHS Ethics Committee (Staff & PGR)

General principles

All research using human participants has to be conducted ethically according to the principles of the Declaration of Helsinki (http://www.wma.net/en/30publications/10policies/b3/) and should be considered by the SHS Research Ethics Committee. The points most relevant for sport and health sciences are given below and are adapted from Ethical Standards in Sport and Exercise Science Research: 2014 Update Int J Sports Med 2013; 34: 1025–1028. (http://sshs.exeter.ac.uk/media/universityofexeter/schoolofsportandhealthsciences/documents/Ethical_Standards_in_Sport_and_Exercise_Science_Research_2014_Update_.pdf)

The SHS ethics form requires confirmation that applications are familiar with both the University of Exeter Research Ethics Framework and the Ethical Standards in Sport and Exercise Science Research: 2014 Update.

1. Basic principles. Respect the rights and welfare of participants which must take precedence over all other interests.

2. Ethical review. Before any research begins and before amendments are applied, research must be reviewed and approved by the Sport and Health Sciences Ethics Committee.

3. The research protocol. The study, research design and statistical analysis must be clearly described, justifiable and appropriate. In drawing up the research protocol, the researcher must;
a) consider ethical issues in accordance with the University of Exeter Research Ethics Framework (http://sshs.exeter.ac.uk/media/universityofexeter/schoolofsportandhealthsciences/documents/Research_Ethics_Framework_v5_Jan_2015.pdf),
b) provide information regarding potential conflicts of interest,
c) consider the contribution to new knowledge and consider the environment,
d) include details of any incentives for participants and provisions for treating and/or compensating participants who are harmed as a consequence of participation in the research study,

4. Consent. Informed consent/assent should be provided freely by the participant and should ideally be in writing. Research that involves children or other populations that cannot consent (e. g. vulnerable populations) should seek consent from an appropriate person and assent from the participant. Informed consent/assent must include the following:
a) aims of the research,
b) methods,
c) sources of funding (if relevant),
d) conflicts of interest,
e) institutional affiliations,
f) anticipated benefits and potential risks,
g) potential discomfort and
h) right to refuse to participate or withdraw consent without reprisal.

5. Conduct. Research must be conducted
a) in accordance with appropriate risk management (see
SHS Health and Safety webpage at:
http://sshs.exeter.ac.uk/students/healthandsafety/)
b) by appropriately qualified researchers and support staff ,
c) with skill and care,
d) in an appropriate setting,
e) in order to protect the privacy of participants and confidentiality of their personal information and
f) in accordance with laws and regulations of the country or countries in which the research is to be performed as well as international norms and standards.

6. Governance. Serious adverse events occurring during the study must be reported to the ethics committee that ethically reviewed and approved the research. The end date of the study should reported to the ethics committee administrator.
http://sshs.exeter.ac.uk/media/universityofexeter/schoolofsportandhealthsciences/documents/currentstudents/SHS_Ethics_Committee_Policy_on_Adverse_Events_v1.pdf

How to prepare and submit your application

To guide your submission to the SHS ethics committee the table below and the notes that follow provide information on what the ethics committee requires in order to make a decision to approve the study or not.

Questions	Considerations
1. Is there a clear research question?	A clear research question is the cornerstone of good research practice. Any project should build on a review of current knowledge. Replication to check the validity of previous research or for education is justified, but unnecessary duplication is unethical. Researchers should explain why the question is worth asking (see Note 1).
2. Will the proposed study design answer the research question? What is the intervention difference?	Researchers should explain how the proposed research method is appropriate for the question posed and how the design will answer the research question (see Note 2). The primary outcome measure should be a clear, quantitative measure of effect that should be plainly and consistently described in the study protocol (see Note 2).
3. Are the assumptions used in the sample size calculation appropriate? Is there evidence and reasoning behind	Researchers must report all the information needed to allow any reader to understand the rationale for the assumptions that have been made and

the design assumptions used in the calculations? Can the calculations be reproduced?	reproduce the sample size. The sample size should always be justified (see Note 3)
4. How will safety and efficacy be monitored during the trial?	Researchers have a responsibility to the study participants to monitor safety and benefit during the study (see Note 4).
5. How will the study results be disseminated? Are there plans to place the project in the public domain by publication?	Ethical research is open. Results should be shared with participants at the end of the study and the procedure for this should be clearly described (see Note 5)

Notes

Note 1. Research Question

Definition of the research question is key to research design. It should be:

- Clearly and consistently stated
- Worth asking
- Based on systematic review of relevant existing evidence

All research must have a primary question, clearly stated in advance. The planning of a study depends on this question and researchers should explain clearly and simply in the study protocol what the study is aiming to show, why it is worth asking and, through consultation with the people representative of possible participants, why this is worthwhile to participants. Researchers should ensure that the primary question is consistently stated throughout the study protocol. Underpinning this, researchers should conduct a systematic review of the relevant existing evidence before starting the study and report this in the protocol. Absence of a systematic review raises the question: what is the design based on?

Note 2. Study Design

Here we are asking, “Will the research, as designed, answer the research question?”
Researchers should be able to:

- Clearly state the research question and the primary outcome measure
- Explain how the research method proposed is appropriate for the question posed, and why it is the best approach
- Provide sound reasoning behind the choice of any intervention difference sought, as well as the other parameters used in the determination of the sample size
- Describe in the study protocol how the relevant successes and failures of previous studies have been taken into account in the design of the planned trial
- Justify the comparators/control condition
- Explain the blinding and randomisation methods (if used), and why the statistical tests applied are suitable
- Show that the sample studied is representative and thus generalizable to the wider group of participants/patients. Inclusion and exclusion criteria need to be adequately described

Note 3. The Sample Size Determination

Research is done to find a solution to a particular problem (formulated as a research question which in turn is) based on statistics. Studies are nearly always undertaken

with limited subjects drawn from the concerned population known as “sample population”. The data obtained is analyzed and conclusions are drawn which are extrapolated to the population under study. Research in sports science is typically done to determine a performance difference between two (or more) interventions/regimens. Whatever the aim, one can only draw reliable conclusions about the magnitude of the difference and the statistical significance if the sample size is large enough to outweigh uncertainty
Sample size is an important issue for ethics committees. An undersized experiment exposes the participants to potentially harmful treatments/intervention and discomfort without advancing knowledge. In an overly large study, an unnecessary number of participants are subjected to a potentially harmful treatment/intervention and discomfort or are denied a potentially beneficial one if in a control or comparison group. Not all “small” studies are unethical, particularly if participant burden is low and the estimated effect has high value, even if “statistical significance” has not been realised. To assist ethics committee reviewers**:**

All study protocols must provide some form of sample size justification.

The calculated sample size is determined by the following factors:
- The variables of interest in your study, including the type of data (e.g. continuous, ordinal)
- The desired power - typically set at 80%, 90% or 95%. Power should not be less than 80%
- The desired significance level – typically set at 5%
- The smallest effect size that would still be deemed important to health or performance
- Aspects of the design of the study: e.g. a simple randomised controlled trial, a cross-over study, repeated measures etc.
- The standard deviation of continuous outcome variables
- The correlation between repeated measures

Therefore researchers need to specify these factors in their submission. Researchers should also show the reviewers that they have solid reasoning behind their calculations The research protocol should include a concise summary of how the assumptions used in the sample size calculation were chosen, reference the source from which they were obtained (published papers or internal pilot studies) and indicate why they are considered plausible for the planned study.

A single or composite primary outcome measure (also called the primary endpoint) should be identified to address the primary question. The primary outcome measure should be a clear, unarguable, quantitative measure of effect. The outcome measure and the time at which it will be measured should be clearly and consistently stated in the study protocol.

Example: ‘ ‘Mean change from baseline to Week 52 in HbA1c level’.

In any study, it is usual to specify one primary outcome measure, considered more important than others, and on which the sample size calculation is normally based. If the sample size is not based on the primary outcome measure, but on a secondary efficacy or safety measure, or sub-analyses, this needs to be clearly explained in the sample size determination. There can be any number of secondary measures, although they should all be relevant to the declared aims of the study. **Researchers**

should clearly describe any treatment/intervention difference they are seeking to detect and present evidence that it is the smallest important difference for the most important effect.

A free online sample size calculator such as G*Power is available to download here.
http://www.gpower.hhu.de

This link will take you to some annotated examples of sample size calculations using G*Power.
http://www.ats.ucla.edu/stat/gpower/

Exceptions to requirements for a sample size calculation include qualitative studies, feasibility studies and pilot studies. The major funding bodies have agreed definitions for feasibility and pilot studies. It is expected that pilot or feasibility studies show a clear route of progression criteria to the substantive/definitive study.

Feasibility studies

Feasibility Studies are done before a main study in order to answer the question "Can this study be done?" They are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size of the substantive study;
- willingness of participants to be randomised;
- ability to recruit participants;
- number of eligible patients/participants; carers or other appropriate participants;
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance .

Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study.

Pilot studies

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome.

Feasibility studies should not undertake inferential statistics or make judgements about the efficacy of an intervention and pilot studies should be cautious about this as they are likely to be underpowered and are primarily designed to inform a more definitive study.

Unacceptable reasons for not undertaking sample size estimates for ethics applications include:

"A previous study similar to the proposed study recruited 15 participants and found highly significant results (p=0.01), and therefore a similar sample size will be used here."
Previous studies may have been 'lucky' to find significant results, due to random sampling variation. Calculations of sample size specific to the present, proposed study should be provided - including details of power, significance level, primary outcome variable, effect size of minimally important difference for the primary outcome, standard deviation (if a continuous variable), and sample size in each group (if comparing groups).

"Sample sizes are not provided because there is no prior information on which to base them."

Every effort should be made to find previously published information on which to base sample size calculations, or a small pilot study should be conducted to gather this information. Where prior information on standard deviations is unavailable, sample size calculations can be given in very general terms, i.e. by giving the magnitude difference that may be detected in terms of a standardised difference.

Note 4. Monitoring safety and efficacy during the clinical study
All studies should be monitored for protocol compliance and adverse effects.
If the intervention is of long duration then evidence of efficacy or harm should be continually monitored to determine if the study should continue. No study should continue to randomise people once the main comparisons have revealed clear-cut differences.

Note 5. Disseminating the results
The ethics committee will expect that access to results will not be unfairly restricted irrespective of the finding and will be made publically available.
The participants in the study should have the opportunity to review the results of the study in a format that is easily accessible to a lay audience.

Completing the ethics application form

Below is a simple view of the ethics application process.

There are two types of application, path A and path B:

Path A applications will:

- Involve low ethical risk procedures, subjects and/or individuals (i.e. 18 years or above, and healthy).
- Not involve children or vulnerable adults.
- Include only non-invasive procedures for human test subjects (Permitted - Capillary blood sampling, blood sampling via venipuncture, blood sampling via cannulation)
- Involve off the shelf nutritional supplements being used according to manufacturer's guidelines.

Path B applications will:

- Include all studies not covered by Path A.

You will need to decide whether your application is Path A or Path B. Section I of the application form will help you make this decision. Section I of the form includes details about the title of the study, what kind of study it is (student or student/staff project), who is involved in the study and their contact details and the name of your dissertation supervisor.

All applicants must at least complete Sections I, II, III & V of this form and section IV if Path B

Please familiarise yourself with the most recent version of the ethics application form before you start to complete it. You can find it here: http://sshs.exeter.ac.uk/intranet/ethics/

- As you go through the application form please ensure that all sections are completed.
- If you are unsure of exact details please enter the information to the best of your knowledge or for boxes that may not be applicable (i.e. Names of Researchers) please enter "Nil" in the field.
- At the end of the document (Section V) you should list the documents that you will be submitting with your application.
- You must provide i/d numbers and descriptions for all relevant Risk Assessments. Staff and PGR students can find our existing risk assessments on the CLES N drive at: N:\Health-Safety\Risk Assessments\SHS , with an Excel index file at N:\Health-Safety\Risk Assessments (**risk assessments for CLES.xlsx**). (Undergraduate and PGT students can find them in their dissertation module ELE pages.)
- Once your application has been emailed to the Ethics Committee Administrator by your Supervisor, if your application is track A it will go to a Committee Reviewer. They will request changes or accept the application. If your application is track B it will go to the Ethics Committee who will then accept or suggest changes.
- The Ethics Committee Administrator will notify you by email of the decision within one week of the submission deadline or Committee meeting.

Things to remember:

- Make sure the name of everyone on the project is included. Please be aware that emails may go to the first name on the study.
- You will need to enter start and end dates for your project. The end date should be the end of the current academic year e.g. July 2015.
- You cannot submit your application to the Ethics Committee Administrator personally – applications will only be accepted if they are submitted by your Supervisor.
- You cannot start collecting your data until you have the email confirming ethical approval.

Ethics Deadlines

Each month there are deadlines for Path A applications to be submitted by (see http://sshs.exeter.ac.uk/intranet/ethics/). All applications submitted that month will be considered after this deadline. If you do not make the deadline, your application will not be reviewed until the next month. Applications may be reviewed before deadlines, but this is at the discretion of each member of staff and is dependent on individual applications. All applications should be reviewed by one week after the deadline. Path B applications are reviewed by the SHS ethics committee who meet less frequently and therefore more time should be allowed for Path B applications.

Preparing a Participant Information Sheet and Informed Consent

The aim of a participant information sheet is to provide enough information about your study, in a clearly understandable format, to help potential participants decide whether they should accept your invitation to participate in your study or decline.

Throughout the document keep your language understandable and in plain English. You can easily check the readability of Word documents by following the simple guide under the Participant Information & Consent section of the SHS ethics website (http://sshs.exeter.ac.uk/intranet/ethics/). For further help with readability see http://www.hra-decisiontools.org.uk/consent/examples.html

Below is a suggestion of the key headings that your PIS should cover. This is only a guide and more detailed information can be found at: http://hra-decisiontools.org.uk/consent/content-sheet-support.html.

An example of a Participant Information Sheet can be found **guide under the** Participant Information & Consent section of the SHS ethics website (http://sshs.exeter.ac.uk/intranet/ethics/).

Study title

Remember: I.P.O.C - Intervention, Population, Outcome, Comparator (if appropriate) is a rule that helps produce a meaningful study title.

Invitation and brief summary

Potential participants should be given very brief information about your study: just enough to decide if they wish to read further.

What's involved?

What is the nature of what you are proposing? Why are you doing this research? What is already known? How many will be involved in the study? Etc.You should try to keep this brief and avoiding cutting and pasting directly from a protocol.

What would taking part involve?

You should give potential participants an idea of what they should expect if they agree to take part. It is important that you consider their perspective and likely view of any impacts on them, their lives and those close to them.

Potential participants need to know what they are being asked to give consent to so be clear.

There will be specific issues pertinent to your particular study and the types of participant you intend to recruit which must be considered here (e.g. adults not able to consent for themselves or children / young people). Specific issues may include:

- Randomisation and blinding

- Screening and exclusion
- Tissue samples
- Research databases and tissue banks
- Expenses and payments
- Exposure to ionising radiation

What are the possible benefits of taking part?

It is likely that you cannot guarantee any specific benefits of taking part, and this should be made clear to potential participant. However, research does deliver wider benefits to society / others with a similar condition and some indirect benefits might be foreseeable for participants themselves.

What are the possible disadvantages and risks of taking part?

You should include details of all significant risks of harm, risks to confidentiality and psychological risk. Some specific issues you should consider include:

- Side effects of treatments / interventions in trials
- Discomfort/fatigue following the intervention
- Discovering health related findings
- Ionising radiation etc.

  Try to describe the likelihood of adverse things happening, as well as severity in language all potential participants are likely to understand.

Further supporting information

Finally you should provide potential participants with more details of what is involved so that you can fully support them in making an appropriate decision. Some of the issues that might be appropriate here include:

- What if something goes wrong?
- What will happen if I don't want to carry on with the study?
- How will my information be kept confidential?
- What will happen to the results of this study?
- Who is organising and funding this study?
- How have patients and the public been involved in this study?
- Who has reviewed this study?
- Further information and contact details
- What to expect during the consent process
- Involvement healthcare practitioner
- What will happen to the samples I give?
- Commercial exploitation etc.

Version control

All of your consent documents (and other study documents) should have a version number and date, to ensure that any changes or amendments can be more easily implemented.

Sport and Health Sciences Ethics Committee Policy on Informed Consent

Purpose

To document the policy and procedures approved by the Sport and Health Sciences Ethics Committee for taking informed consent from participants in:

- Studies conducted by undergraduate and postgraduate students as part of the dissertation requirement on taught courses.
- Research projects conducted by staff and postgraduate students.
- To provide examples of best practice in the construction of consent forms and participant information sheets.

Abbreviations Used

SHS	Sport and Health Sciences
CLES	College of Life and Environmental Sciences
PIS	Participant Information Sheet
EC	Ethics Committee

Scope

This policy applies to:

- Staff of SHS
- Undergraduate and postgraduate students of SHS

Policy and Procedures

The SHS EC expects all staff and students of SHS to follow best practice in obtaining Informed Consent from participants in research and dissertation projects. To this end the PIS and Informed Consent forms for each project are required to be submitted as part of the ethical approval application process. These documents will be scrutinised by the individual reviewer in the case of path A applications and by the EC in the case of path B applications.

Examples of an Informed Consent form can be found in the documents listed below under Further Information and at this link: http://sshs.exeter.ac.uk/intranet/ethics/

In the case of studies involving children or vulnerable adults applicants should submit both the assent form to be signed by the child / vulnerable adult and the consent form to be signed by the parent or guardian.

The SHS EC recommends that all staff and students enrolling participants in research and dissertation projects receive appropriate training in Informed Consent. For studies involving the sampling and storage of any material which contains intact human cells it is a requirement of the Human Tissue Authority that a formal training course in Informed Consent be undertaken by those taking consent from participants. Applications for ethical approval for such studies must be submitted via path B and the SHS EC will require evidence that such training has been undertaken.

A database of staff and students who have undertaken training courses in Informed Consent is maintained by the SHS EC administrator.

Further Information

Further detailed information on Informed Consent procedures can be found in the following two documents:

1. The St Lukes Laboratories general manual on procedures required for compliance with the requirements of the Human Tissue Authority: *HTA Management Document V9 March 2015*

2. St. Lukes Tissue Handling Standard Operating Procedure (SOP) no. 7: *Taking Informed Consent V2*

Both documents can be found on the UEMS network drive at the following location: \\isad.isadroot.ex.ac.uk\uoe\Research\UEMS\UoE HTA .

Beginning Testing

You cannot begin testing until you have received confirmation that your application has been successful .

If you have any queries about the ethics process please contact the ethics committee administrator: mailto:shs-ethics-admin@exeter.ac.uk