Cardiff Metropolitan University
Obtaining ethics approval for your research project

Cardiff Metropolitan University has the responsibility to ensure that all research involving human participants carried out by its staff and students conforms to the highest ethical standards. In this context, research is defined as an activity to gather information for dissemination, either through publication, dissertation, thesis, or report. For the purpose of these guidelines it includes all enterprise activities involving human participants.

Responsibility for this lies with the University Ethics Committee (UEC) which has a remit to ensure that the institution acts in an ethical manner at all times, adhering to the principles laid down in the University's Ethics Framework.

Routine scrutiny of applications for ethics approval has been delegated to School based ethics committees which report directly to UEC. Any appeals against a decision made by a School ethics committee will be considered by UEC. The appeals process is fully detailed on the University website.

The principles upon which decisions regarding applications for ethics approval are made are as follows:

- Research on human participants must be beneficial.
- Participants have the right to expect that research is well planned and is likely to lead to an outcome that will be beneficial.
- Research should avoid doing harm wherever possible.
- Researchers must make every effort to respect the autonomy of participants.
- Where participants have limited autonomy, special precautions must be taken to safeguard their dignity and rights.

Does my project require ethics approval by committee?

All research requires that ethical considerations are addressed, however formal approval from a School's ethics committee or 'gatekeeper' acting on its behalf is only required if the proposed project deals with human participants or human tissue, is sensitive, deceptive or covert.

Process for submitting an application for ethics approval

Applications for student projects must be completed by the student themselves, acting as Principal Investigator (PI) but must be endorsed by the supervisor.

School committees meet on a regular basis although meetings may be less frequent outside term time. You should consult the University website for details of meeting dates for your School committee.

The deadline for submission of an application for ethics approval is normally five working days prior to a meeting. It should be noted that applications received after the deadline will only be considered under exceptional circumstances.

Why an application may be returned to the PI

Where possible, and within given time constraints, a member of the relevant ethics committee will contact the PI in advance of the meeting with details of any major omissions or factors in the application which make favourable review unlikely.

Additional material may be sent at this point, providing it is prior to the submission deadline.

The approval process

If adequate information has been submitted, your application will be sent to committee members who will review it and present their comments at the meeting.

Following the meeting, you will be sent a letter notifying you of the committee's decision[1]. Every effort will be made to notify the PI as soon as possible. Decisions are categorised as follows:

Approved:	The application is satisfactory and needs no amendment or correction.
Approved in Principle:	The application is essentially ethically sound, however the PI needs to make some minor amendments before it can be approved (normally by Chair's action).
Deferred:	The Committee could not reach a decision and need to seek further advice.
Not Approved:	The application is seriously flawed and requires major revision before it can be reconsidered. Protocols in this category have to be considered by the full Committee if resubmitted.
Rejected:	The study is deemed unethical.

If approval is deferred or is given "in principle", the letter will outline the amendments necessary to secure approval. Once the amendments have been made, you will need to resubmit the amended pages. In response, you will be sent a letter confirming that the revised submission has been approved or explaining why it has not been.

Approval is given for one year for all undergraduate and Masters level studies. For other studies, approval will be given for up to three years depending on the expected duration of the project. Once approval has expired, an extension may be sought if required. This will not require a full re-application and can normally be approved by Chair's action.

[1] For student projects, the supervisor will also be notified.

CARDIFF METROPOLITAN UNIVERSITY
APPLICATION FOR ETHICS APPROVAL

When undertaking a research or enterprise project, Cardiff Met staff and students are obliged to complete this form in order that the ethics implications of that project may be considered.

If the project requires ethics approval from an external agency such as the NHS or MoD, you will not need to seek additional ethics approval from Cardiff Met. You should however complete Part One of this form and attach a copy of your NHS application in order that your School is aware of the project.

The document ***Guidelines for obtaining ethics approval*** will help you complete this form. It is available from the Cardiff Met website.

Once you have completed the form, sign the declaration and forward to your School Research Ethics Committee.

PLEASE NOTE:
Participant recruitment or data collection must not commence until ethics approval has been obtained.

PART ONE

Name of applicant:	Click here to enter text.
Supervisor (if student project):	Click here to enter text.
School:	Click here to enter text.
Student number (if applicable):	Click here to enter text.
Programme enrolled on (if applicable):	Click here to enter text.
Project Title:	If using a working title, it should convey what the project is about
Expected Start Date:	Click here to enter a date.
Approximate Duration:	Click here to enter text.
Funding Body (if applicable):	Click here to enter text.
Other researcher(s) working on the project:	If your collaborators are external to Cardiff Met, include details of the organisation they represent.
Will the study involve NHS patients or staff?	If yes, attach a copy of your NHS application to this form
Will the study involve taking samples of human origin from participants?	Choose an item.

In no more than 150 words, give a non technical summary of the project
Click here to enter text.

Does your project fall entirely within one of the following categories:	
Paper based, involving only documents in the public domain	Choose an item.

Laboratory based, not involving human participants or human tissue samples	Choose an item.
Practice based not involving human participants (eg curatorial, practice audit)	Choose an item.
Compulsory projects in professional practice (eg Initial Teacher Education)	Choose an item.
If you have answered YES to any of these questions, no further information regarding your project is required. If you have answered NO to all of these questions, you must complete Part 2 of this form	

DECLARATION: **I confirm that this project conforms with the Cardiff Met Research Governance Framework**	
Signature of the applicant:	Date:
FOR STUDENT PROJECTS ONLY	
Name of supervisor:	Date:
Signature of supervisor:	

Research Ethics Committee use only	
Decision reached:	Project approved ☐ Project approved in principle ☐ Decision deferred ☐ Project not approved ☐ Project rejected ☐
Project reference number: Click here to enter text.	
Name: Click here to enter text.	**Date:** Click here to enter a date.
Signature:	
Details of any conditions upon which approval is dependant: Click here to enter text.	

PART TWO

A RESEARCH DESIGN	
A1 Will you be using an approved protocol in your project?	Choose an item.
A2 If yes, please state the name and code of the approved protocol to be used[1]	
Click here to enter text.	
A3 Describe the research design to be used in your project	
In this section, include details (as appropriate) of: - research method(s); - sample and sampling; - recruitment of participants; - analytical techniques If your project does involve the use of an approved protocol, much less detail will be required but you should indicate which areas of the project are covered by the protocol.	
A4 Will the project involve deceptive or covert research?	Choose an item.
A5 If yes, give a rationale for the use of deceptive or covert research	
Click here to enter text.	

B PREVIOUS EXPERIENCE
B1 What previous experience of research involving human participants relevant to this project do you have?
Click here to enter text.
B2 **Student project only** **What previous experience of research involving human participants relevant to this project does your supervisor have?**
Click here to enter text.

C POTENTIAL RISKS
C1 What potential risks do you foresee?
Include details of risks to the participants, the researcher and the project as a whole.
C2 How will you deal with the potential risks?
Click here to enter text.

When submitting your application you **MUST** attach a copy of the following:

- All information sheets
- Consent/assent form(s)

Refer to the document ***Guidelines for obtaining ethics approval*** for further details on what format these documents should take.

[1] An Approved Protocol is one which has been approved by Cardiff Met to be used under supervision of designated members of staff; a list of approved protocols can be found on the Cardiff Met website here

CARDIFF METROPOLITAN UNIVERSITY
Completing an application for ethics approval – guidance notes

These guidance notes are to assist staff and students completing an application for ethics approval.

Part One

Project Title
This should capture the essence of the project for a non-specialist audience. Please remain consistent throughout. If you plan to use a shorter version of the title (for instance on the consent forms or information sheet) in addition to the full format title of the project, please include both in this box.

Expected Start Date
Participant recruitment and/or data collection must not start until ethics approval has been given and this should be reflected in the preferred start date. Under exceptional circumstances it may be possible for a project to be given urgent consideration (ie to meet the deadline of a funding body). If you wish to appeal for urgent review, please submit a covering note explaining why this is necessary.

Funding Body
Provide details of any body from which you have received or will be receiving funding in relation to this project.

Other researcher(s) working on the project
All other collaborators / investigators should be listed.
If any collaborators are students provide details of the qualifications he or she is working towards.
If any collaborators are from other institutions please give details of their institution and explain their role in this project.

Will the study involve NHS patients or staff?
Most studies involving NHS patients or staff will require approval from the NHS and will not require additional approval from Cardiff Met. If you are unsure if your project will require NHS approval, contact the Chair of your school research ethics committee.

If you are required to submit your application to the NHS, attach a copy to your Cardiff Met ethics approval form to be kept on record by the School research ethics committee. Your School committee will accept the completed NHS application and letter of approval in lieu of Cardiff Met approval.

In some instances, the NHS will not classify your project as research and will return your application. In this instance you must seek ethics approval from Cardiff Met via your School committee. Your School committee will require sight of the letter confirming exemption from NHS ethics processes.

Will the study involve taking samples of human origin from participants?
For research involving the use or storage of samples of human tissue or the use of stored samples of tissue, projects must comply with all codes of practice regarding the taking, use of and storage of human tissue.

Non technical summary of the project
Provide the academic justification and background of the study and state the anticipated benefits of researching your chosen area. It may be helpful to refer to related studies.

Part Two

A1 Will you be using an approved protocol in your project?
Approved Protocol status may be awarded to certain standardised procedures to be used in research projects under the supervision of designated members of academic staff. Generally this simplifies the application process. A list of approved protocols and designated supervisors can be found on the Cardiff Met website. Students should liaise with their supervisor to decide if they are eligible to use an approved protocol in their study.

A2 If yes, please state the name and code of the approved protocol to be used
Please ensure that the approved protocol name and code are listed on the Cardiff Met website as approved protocol status **MUST** be current at the time of application.

A3 Describe the research design to be used in your project
Describe your project's overall design and the method of data collection which will be used.

The nature of your project may mean that changes in the approach or direction may be necessary as the research develops. Please indicate if this is the case and describe as fully as possible the start out approach and direction.

Provide a brief summary of the nature of the participants' involvement in order for the committee to understand exactly what will happen to the participant.

The following points should also be clarified:
- Why is it necessary
- Where the interaction will take place
- How long each session will take
- How many sessions participants will have to attend
- How long the interval between sessions will be

If your data collection will involve the use of a questionnaire, you should provide a copy of the questionnaire with your application. In cases where the questionnaire has not yet been finalised you should give examples of the kinds of questions which participants will be answering. Similarly, if your data collection will involve the use of focus groups, you should provide details of the topics which will be discussed.

Describe the methods and techniques which will be used in the analysis of the results.

Generally, the University expects researchers to take an inclusive approach to recruitment of participants. It would be helpful therefore to give details of any limitations on which groups can participate in the project and include reasons for adopting these limits.

In the case of projects involving groups, please give details of what will happen to excluded participants.

For quantitative research projects, state and give full justification for the number of participants you plan to recruit.

A4 Will the project involve deceptive or covert research?
and
A5 If yes, give a rationale for the use of deceptive or covert research

Deceptive and covert research is generally undesirable because it violates the principle of voluntary informed consent, and in some circumstances may be illegal. However, it may be the only practical way to gather important information; for example, where awareness of being observed would alter the behaviour of subjects sufficiently to invalidate the research. In order to be approved, projects must fully meet the following conditions:

1. There is a strong case that the research is worth doing.

2. There is a strong case that covert research is essential to gain the required information (ie that there are no alternative methods available that are not deceptive or covert).

3. Once the period of covert observation has been completed, the agreement of each participant will be required before any data relating to the individual can be included in the research analysis. This will only not apply in cases where this is impractical (for example, where a public place has been observed with transient subjects being impossible to trace) and data gathered can not be related to any individual observed.

4. No permanent record will be kept of any personal information which could possibly lead to the identification of a participant, unless the individual has been told that the information has been acquired during the course of the research and has agreed to its retention.

B1 What previous experience of research involving human participants relevant to this project do you have
and
B2 What previous experience of research involving human participants relevant to this project does your supervisor have?

It is vital that you give details of previous experience of research involving human participants relevant to the proposed project. In the case of a student project, this information should be provided in respect of the supervisor.

Members of the ethics committee will refer to this information to ensure that the PI (and/or the supervisor in the case of student projects) has sufficient relevant experience of the type of project to be carried out. Information should therefore be provided illustrating previous experience which is relevant to this application. This should include specific details of previous use of the same project design, particularly where the project has resulted in published outputs. For supervisors, specific details of supervision of previous similar projects would be helpful.

C1 What potential risks do you foresee?

Describe the potential hazards, risks and adverse effects for participants in the research, specifying the probability and seriousness in each case. For research involving interviews and questionnaires, any risk of psychological or social ill effects should be considered.

If the study design has been informed by statistical power calculations an indication as to the basis on which this was done should be provided.

If possible, you should complete a standard Cardiff Met Risk Analysis for the project. This should however **be in addition to** the provision of a full response to this question.

If your project will involve invasive procedures, please provide details such as:

- where the procedure will take place;
- what facilities are available;
- what size of sample will be taken (eg amount of blood taken, size of dose administered);
- where will samples be stored and how will they be identified;
- who will have access to the samples.

Also consider any potential risks you may be exposed to. These should include risks due to any procedures being carried out (eg collection of blood samples, use of equipment) or to the environment in which you will be working (eg field work situations)

Finally, you should consider any risks to the project itself.

C2 How will you deal with the potential risks?
Explain the methods you will use to reduce the risks detailed in C1 and measures that will be taken to ensure the safety of participants in the event that any identified risks eventuate

Gaining consent from participants

It is generally acknowledged that robust research ethics requires the voluntary consent of human participants/subjects. Potential participants/subjects in research projects must normally have the right to choose whether or not they will participate. Fully informed consent in this context means consent which is freely given with proper understanding of the nature and consequences of what is proposed and what is likely as a result.

The following process is recommended to ensure that this is in place:

- Each participant should be given an oral explanation of what participation in the project will entail.
- Each participant would then be given an information sheet explaining in simple, non technical terms, the background to the project, the procedures involved, any potential risks and hoped for benefits.
- The participant should be given reasonable time to consider this information and to consult others as necessary.
- Except in the case of questionnaire based studies, the participant should be asked to sign a consent form. In the cases where participants are either children or "vulnerable" adults, consent should normally be gained from a properly empowered proxy with the participant giving informed assent.

For research involving the use of samples of human tissue or the use of stored samples of tissue, you must attend the University training on the taking of consent before commencing your project. For further details refer to the University's Code of Practice for obtaining informed consent in respect of research study participation which is available on the ethics pages of the University's website.

Written consent from participants will normally be required for all studies except those that are exclusively based on questionnaires and are not collecting sensitive data. In these cases, submitting a completed questionnaire implies consent and this should be stated on the information sheet given to participants .

The standard position in the ethics advice of most learned societies is that informed consent should be obtained wherever possible. Your School may provide guidelines about research situations where the conventions of obtaining informed consent do not usually apply, or where a different approach to obtaining written consent is generally accepted.

If verbal consent, and not written consent, is to be obtained, please indicate this and complete the participant information sheet with the information that you intend giving to participants verbally.

If you do not intend obtaining consent at all you must provide a full justification for this. Please note, a strong justification is needed, either in terms of the benefits of the study, or of the research approach, before a school ethics committee will consider allowing a project to proceed without informed consent

If it is proposed that research be conducted on adults who may not be able to give fully informed consent on their own behalf (eg people with dementia), justification for this must be clearly stated in your application for ethics approval.

Although consent can not be given on behalf of another, it is important to inform and/or enlist the support of those involved in the care of vulnerable individuals.

Where appropriate, letters to parents, teachers and medical staff should be provided.

Projects involving participants under the age of 18

Generally, the University requires that both the assent of the child and the consent of the parent or guardian are obtained prior to commencement of the project. Separate information sheets should be provided for parents and children to take account of their different cognitive abilities.

Child assent should be sought in a way which is appropriate to the age and ability of the child. For example, in the case of younger children, this may involve the use of pictures to signify how the child feels about participating the project

Projects involving very young children
Child assent is not needed in cases where the children involved are too young to understand a simple explanation of the research to be undertaken eg observational projects involving very young children of less than 18 months old. In such cases, the project may proceed with parental consent only.

Participants who are aged between 16 and 18 years old are minors but generally considered to be competent for the purposes of gaining consent. It may however be highly desirable to obtain parental consent for some projects involving participants in this age group. In other cases, the research involved may be clearly innocuous and not require parental consent. If your project involves participants in this age group and you do not intend requesting consent from parents, please justify this.

School / community based projects
Often, projects involving participants under the age of 18 will involve a group of pupils from a school or a group of attendees at, for example, a youth club. In such cases, consent should also be sought in writing from the head of the school or organisation from which the participants will be drawn. The letter requesting consent should include details of the project (including the questions which participants will be asked) and the involvement of the school / group. The committee will require sight of the written consent given by the head of the organisation before giving ethics approval to your project.

In the case of school or community based projects, the University will normally expect you to gain informed parental consent in addition to the consent of the head of the organisation. However, it is recognised that, in some cases, this could represent a large administrative burden and often leads to difficulties for the school. Thus, in projects dealing with issues which could be considered "public" eg discussions about views on music or sport, consent may be gained solely from the head of the organisation acting in loco parentis. For projects dealing with issues focussed on the personal or family life of participants, due to the nature of the subject matter, parental consent must be sought. In all cases, the assent of the participants themselves must be obtained.

For further information on research projects involving children, please refer to the guidance for researchers produced by the National Children's Bureau available from the "research" section of the NCB website, www.ncb.org.uk .

See Appendix 1 of this document for an example consent form which can be adapted to fit your project.

Participant Information Sheet

A copy of the participant information sheet you will use must be submitted with your application form. These are vital and must be completed carefully.

The information sheet should be written clearly using simple words, sentences and paragraphs. The use of jargon and acronyms should be avoided and any which are used should be accompanied by a clear explanation. As a guide, you should expect a ten year old to be able to read and understand the information. You should make the information as personal as possible using words such as we, you and your child rather than using impersonal terms such as participant or student.

You should make clear to participants that both the information sheet and the consent form can be made available in a variety of formats eg large print, Braille, audio, and in languages other than English.

The information sheet should contain:

- Title of project and ethics approval reference number
- Paragraph 1
  Begin by making clear that this is a study in which the volunteer is being requested to participate and that such participation is entirely voluntary.
- Paragraph 2
  Explain, using straightforward language, the nature and aims of the research project and describe the expected benefits to the volunteer and/or others.
- Paragraph 3
  Explain clearly what will happen to the participant if he/she volunteers to take part and how long the participant's involvement is likely to last. If you are using an Approved Protocol, the wording for participant information included in the Approved Protocol must be included. (see A1 & A2 above)
- Paragraph 4
  Detail any exclusion criteria which apply in order to avoid inappropriate recruitment.
- Paragraph 5
  Give details of any risks, inconvenience or discomfort that may reasonably be anticipated.
- Paragraph 6
  Explain any hoped for benefits to the volunteer which may arise as a result of their participation.
- Paragraph 7
  Provide full details of any financial inducements that are to be offered to participants including:

Payment of expenses:	the committee will normally agree to the reimbursement of reasonable expenses to cover travel and refreshments
Recompense for	the committee will normally agree to this where time commitment is

time commitment:	expected to be substantial. An appropriate rate would be the norma expected hourly rate of pay for the participant.
Financial incentives:	the committee will closely scrutinise any financial incentives considered as disproportionate to the time involved. This is to avoid situations where participants are induced to undertake risks that might otherwise be against their better judgement.

- Paragraph 8
  Provide an indication of the level of anonymity and confidentiality of personal information that can realistically be guaranteed. To ensure compliance with the Data Protection Act, participants must be informed of what information will be held about them and who will have access to it.

If you are intending to collect information classified as sensitive personal data[1] which is identifiable or could potentially be traced back to an individual, you must inform participants of this and gain specific written consent from them.

If your study is questionnaire based, consent to participate will be implied by completion of the questionnaire, a separate consent form is therefore not required. If you are not collecting sensitive personal data you should state on the Information Sheet that submission of a completed questionnaire implies consent to participate in the project. However, if your questionnaire will require the disclosure of this type of information, you should include the following statement in the body of your questionnaire:

"I consent to the processing of my personal information for the purposes of this research study. I understand that such information will be treated as strictly confidential and handled in accordance with the provisions of the Data Protection Act 1998.2"

Provide the name and contact details of the person participants should contact in an emergency and who they should contact to obtain further details about the project. You should provide your contact details at the University and NOT your personal email address or mobile phone number. Students are advised to include University contact details for their supervisor.

See Appendix 2 of this document for an example of an information sheet which was highly commended by a school ethics committee in the past and which you may find helpful to refer to when compiling an Information Sheet for your project.

[1] The Data Protection Act 1998 classifies sensitive personal data as consisting of information as to
a) the racial or ethnic origin of the data subject
b) political opinions
c) religious beliefs or other beliefs of a similar nature
d) membership of a trade union
e) physical or mental health condition
f) sexual life
g) the commission or alleged commission of any offence
h) any proceedings for any offence committed or alleged to have been committed, the disposal of such proceedings or the sentence of any court in such proceedings
www.legislation.hmso.gov.uk/acts/acts1998/19980029.htm

Appendix 1
Exemplar Consent Form

(Form to be on headed paper)

PARTICIPANT CONSENT FORM

Reference Number:
Participant name or Study ID Number:
Title of Project:
Name of Researcher:

Participant to complete this section: **Please initial each box.**

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐

1. I agree to take part in the above study. ☐

The following statements could also be included on the consent form if appropriate:

2. I agree to the interview / focus group / consultation being audio recorded ☐
3. I agree to the interview / focus group / consultation being video recorded ☐
4. I agree to the use of anonymised quotes in publications ☐

_____ _____
Signature of Participant Date

_____ _____
Name of person taking consent Date

_____
Signature of person taking consent

** When completed, 1 copy for participant & 1 copy for researcher site file*

Appendix 2
Exemplar Participant Information Sheet

Reference number: XXXXXX

Title of Project: Do Activity, Stay Healthy - Evaluation

Parent / Guardian Information Sheet

Background

This evaluation project is an attempt to understand the effectiveness of the Do Activity, Stay Healthy (DASH) programme. Commissioned by Somerset Activity and Sports Partnership (SASP), it is being undertaken by The Institute for Vocational Exercise And Sport Training (InVEST) - the enterprise unit of the Cardiff School of Sport at Cardiff Metropolitan University.

In brief, DASH is concerned with increasing levels of activity and with healthy nutrition for children. The project is an evaluation of whether DASH is doing this as effectively as it might. There are two areas that the project will examine:

(i) whether the DASH programme has brought about changes amongst the children taking part; and
(ii) as a family, what your experiences were of the DASH programme.

The evaluation will be presented as a report to SASP and might also be published.

Your child's participation in the research project

Why your child has been asked

Your child has been invited to take part in the DASH programme because it is thought that s/he will benefit as a result. We will be following the progress of all the children who agree to take part starting in 2009. Your child would be one of those.

What would happen if you agree for your child to join DASH?

If you agree for your child to join the study, there are three main things that will happen.

1. You'll be visited in your home by the school nurse. Your child will have some measurements taken (height, weight and waist size), and you'll be asked to answer questions about your own health and lifestyle. This is like a health MOT for your family.
2. Your child will begin attending the DASH programme at school. This happens before the school day on three mornings per week. There is some exercise and then a healthy breakfast. The physical activity sessions are led by qualified coaches from SASP. One of the sessions will be a 'bleep test'. This involves running until your child wants to stop. It doesn't last long, but gives an indication of stamina. This test and the measurements taken by the nurse will be repeated after six weeks and again at the end of the programme (after six months).
3. At the end, we might ask you to talk to us, as a family, about the DASH programme and your experiences of it.

Are there any risks?
We do not think there are any significant risks to your child from taking part in the evaluation study. If s/he is feeling unwell, we'd advise that s/he doesn't take part. And in any case, s/he should do anything that s/he doesn't want to – just tell us.

What happens to the results of the evaluation?
The measurements that are taken at the start and then repeated twice more will be stored securely in locked filing cabinets at the University. They will be coded so that we can remove names, but we need to keep a record of the codes to compare each child's measurements / scores. We will present this information together for all of the children, but there will be no description that would identify individuals. We don't intend to talk to all families (that would take too long), but if you are invited to have the family discussion with us, we will also remove any description of you, your family, where you live, and so on. You will not be identifiable in this part of the work either.

We will present a report to the Somerset Activity and Sports Partnership, and might also write research papers for publication (in journals like *Managing Leisure* and *Pediatric Exercise Science*).

Are there any benefits from taking part?
Yes, you will receive a family health MOT. Your child will learn about exercise and physical fitness, and will also be given healthy breakfasts three times each week while they are involved in the DASH programme. There is no cost to you for any of this.

What happens next?
With this letter you'll find an information sheet for your child. There are also two forms to complete. The first is for you to give permission for your child to be involved in the DASH programme. The second is a different form for your child to complete to confirm that s/he is willing to take part. If you are willing for your child to participate, and s/he is too, these forms should be completed when the school nurse makes the first visit.

How we protect your privacy:
As you can see, everyone working on the study will respect your privacy. We have taken very careful steps to make sure that you cannot be identified from any of the information that we have about you.

All the information about you and your child will be stored securely away from the consent and assent forms. At the end of the evaluation study we will destroy the information we have gathered about you and your child. We will only keep the consent and assent forms with your name and address. We keep these for ten years because we are required to do so by the University.

Further information
If you have any questions about the research or how we intend to conduct the study, please contact us.

Title, name and role
☎ 02920 ******
✉ **********@cardiffmet.ac.uk

UREC reference number: XXXXXX

Title of Project: Do Activity, Stay Healthy - Evaluation

Child Information Sheet

Welcome to DASH!
DASH is a project that is about helping children become more healthy. It's partly about taking more exercise and getting fitter, and partly about eating healthy food. We want to find out if DASH is working, so we want to find out two things:

1. whether DASH works for you – we want to start this very soon;
2. what some families think about DASH – we want to do this at the end.

Why you?
You are being asked because we think you might be someone who could learn a lot about exercise and healthy eating if you take part.

What will happen?
DASH lasts for six months. At the very start a nurse will come to your house to see how tall you are, how heavy you are and take your waist measurement. After that you start the early morning DASH club where you do some exercise and have a healthy breakfast. This happens three times a week. One of the first things you'll do there is a bleep test where you run around until you want to stop – it doesn't last very long. After six weeks the nurse will take your measurements once more, and again after six months. You'll do the bleep test twice more as well.

After you've done this, we might ask you and your family to talk to us altogether about what you think of DASH.

Do I have to?
No, you don't. No-one is forcing you. And if you start and decide you don't want to carry on, that's fine. There's no problem, just tell us.

What do we do?
When we've got our information we will write a report for the people who pay for DASH. We might also write something for a book or a magazine. If we do this, we won't say who took part. No-one will know it's you or your family.

Have you got any questions?
If you have any questions just ask. You can ask us yourself, or you can get your parent or guardian to ask us.

Title, name and role
☎ 02920 ******
✉ **********@cardiffmet.ac.uk

Appendix 3
Guidelines for the production of posters, leaflets and emails for participant recruitment

1. Recruitment of participants should be undertaken in such a way that participation is truly voluntary and there is no coercion, either explicit or implicit.
2. The committee prefers the use of indirect approaches rather than face to face individual requests to potential volunteers. Ideally individuals should be able to take a positive step to participate rather than have the discomfort of declining a direct approach.
3. Posters and leaflets may be used to recruit participants. The material can fall into several categories:
   - Posters displayed within the University
   - Posters displayed in other institutions (although recruitment on NHS premises would require NRES or MREC approval)
   - Leaflets
   - Advertisements in newspapers, magazines etc
4. Care should be taken when writing copy to consider the nature of the target group, ensuring that appropriate terminology is used. This is especially important for material likely to be seen by vulnerable groups, and especially for advertisements that are to be published in large circulation magazines etc.
5. A good poster/leaflet or advert should have the following characteristics:
   - The material should be visually attractive with a short clear heading in the form of an invitation and may include illustrations
   - Sufficient information should be given for potential participants to know roughly what is involved
   - Adequate information for making contact should be given
   - Reimbursement of costs and financial incentives may be mentioned but must comply with the guidance given in the section *What remuneration (if any) will be offered to participants?*
6. The committee requires that all posters/leaflet:
   - Carry identification to allow reference to the records held by the committee The minimum requirement is: project ref no *** (*** = reference number)
   - Comply with the reimbursement and financial incentives guidance given in the section *What remuneration (if any) will be offered to participants?*
   - A copy of the poster must be sent to the committee to be deposited with the application papers, for review by the committee and must be approved before use.
   - Posters to be displayed in other institutions outside the University must be sent, with a covering letter, to the administrative officers of that institution for information
7. Recruitment emails should also meet with these requirements. Additionally, they should be short, the participant box should contain a word or two about the study followed by ' – circular', and the email should start with the sentence:

   'Circular email for use for recruitment of volunteers for study ref xx/cc, approved by the [insert name of School] Ethics Committee (or refer to relevant project ref number and Research Ethics Committee). This project contributes to the University's role in conducting research, and teaching research methods. You are under no obligation to reply to this email, however if you choose to, participation in this research is voluntary and you may withdraw at anytime.'

   Proposed emails should be provided to your School committee for approval. A justification for using this means of participant recruitment, and proposed target mail lists should also be provided. An email must be approved before it can be circulated.

Appendix 4
Code of Practice for storage of all samples of human origin

1. Before any research activity involving human derived material (in which the material will be stored overnight) can proceed the notification form (Intention to conduct Research Using Human Derived Material) must be completed and returned to the Designated Individual (Professor Ken Jones) or one of the site specific Persons Designated (Sean Duggan, Llandaff, or Dr Michael G Hughes, Cyncoed). Approval must be given and a project code issued before any such research activity can commence. This code will form part of the sample identification code.

2. All such samples must be stored in accordance with QAA guidelines for research, or if part of a project which has NRES (LREC) approval, in line with research governance criteria.

3. All samples must be logged and their location identified in the database provided on the HTA SharePoint site.

4. All samples must be assigned a unique code prior to storage. This code identifies the unit, the investigator and the subject from whom the sample has been obtained. A record of these samples must be maintained until their disposal.

5. The coding system should include the project code e.g CSHS/KPJ/1/ followed by a numeric identifier for the sample. Thus CSHS/KPJ/1/123

6. All samples obtained from human volunteers are required to show evidence of written informed consent in accordance with the NRES guidelines if covered by LREC approval. University based projects are covered by University ethical approval for which written informed consent is mandatory. Consent forms must be stored centrally in a locked filing cabinet together with all other relevant documentation until the samples are disposed of. Therefore all consent forms that accompany samples must be sent to the Research Administrator in CSHS for safe keeping. These forms MUST include the code number of the sample. ALL PERSONS taking consent MUST have received documented training in the taking of informed consent from human participants. This is a condition of our licence and there are no exceptions. Consent forms and participant information MUST be provided in a variety of formats e.g. large print for partially sighted individuals Braille or audio and other languages if required.

7. All samples of human origin must be stored in locked laboratories in locked fridges and freezers. All records related to such samples must be stored separately in locked filing cabinets. Databases relating to these samples which contain identifying information relating to the donor can only be maintained on password protected computers in offices which are always locked when unoccupied. All fridges and freezers where critical samples and reagents are stored must be equipped with data-logging alarm systems which alert appropriately trained staff on a 24 hours basis.

8. Disposal of samples must adhere to the guidelines for safe disposal of clinical waste and samples must be logged out in the same logbook in which they were logged in. Once samples have been disposed of and any analysis completed the Research Administrator in CSHS must be informed so that the consent forms can be destroyed.

9. All processes relating to the collection, storage and use of human derived material MUST comply with the University's Governance and Quality systems. Appropriate documentation

for all activities must be provided and stored with the project file. All persons involved in any licensable activity must provide a c.v. and evidence of training in all procedures they employ. SOP's must be produced and regularly updated for all such activities. All equipment used must have valid calibration and maintenance records. All required documentation must be stored in the project file along with consent forms and completed notification of intention to conduct research using human derived material. This file will be maintained by the Research Administrator in the School Research and Enterprise Support Office in CSHS or CSS as appropriate.

10. There are no exceptions whatsoever to the above requirements. Thus any student projects involving human derived material MUST comply with the above.

11. Since the requirements of Local Research Ethics Committees under the auspices of NRES are identical to those required by the HTA we would expect that the above practices are followed for any samples collected, stored and processed under such approval.

Compliance with this code of conduct will be audited on a regular basis. Failure to adhere to it will constitute a breach of the University's licence conditions. Such breaches may lead to the revoking of the University's licence and the criminal prosecution of the offender. Individuals are personally liable for failures to comply with the Human Tissue Act.

Exemplar Participant Information Sheet

Reference number: XXXXXX

Title of Project: Do Activity, Stay Healthy - Evaluation

Parent / Guardian Information Sheet

Background

This evaluation project is an attempt to understand the effectiveness of the Do Activity, Stay Healthy (DASH) programme. Commissioned by Somerset Activity and Sports Partnership (SASP), it is being undertaken by The Institute for Vocational Exercise And Sport Training (InVEST) - the enterprise unit of the Cardiff School of Sport at Cardiff Metropolitan University.

In brief, DASH is concerned with increasing levels of activity and with healthy nutrition for children. The project is an evaluation of whether DASH is doing this as effectively as it might. There are two areas that the project will examine:

(i) whether the DASH programme has brought about changes amongst the children taking part; and

(ii) as a family, what your experiences were of the DASH programme.

The evaluation will be presented as a report to SASP and might also be published.

Your child's participation in the research project

Why your child has been asked

Your child has been invited to take part in the DASH programme because it is thought that s/he will benefit as a result. We will be following the progress of all the children who agree to take part starting in 2009. Your child would be one of those.

What would happen if you agree for your child to join DASH?

If you agree for your child to join the study, there are three main things that will happen.

1. You'll be visited in your home by the school nurse. Your child will have some measurements taken (height, weight and waist size), and you'll be asked to answer questions about your own health and lifestyle. This is like a health MOT for your family.
2. Your child will begin attending the DASH programme at school. This happens before the school day on three mornings per week. There is some exercise and then a healthy breakfast. The physical activity sessions are led by qualified coaches from SASP. One of the sessions will be a 'bleep test'. This involves running until your child wants to stop. It doesn't last long, but gives an indication of stamina. This test and the measurements taken by the nurse will be repeated after six weeks and again at the end of the programme (after six months).
3. At the end, we might ask you to talk to us, as a family, about the DASH programme and your experiences of it.

Are there any risks?

We do not think there are any significant risks to your child from taking part in the evaluation study. If s/he is feeling unwell, we'd advise that s/he doesn't take part. And in any case, s/he should do anything that s/he doesn't want to – just tell us.

What happens to the results of the evaluation?
The measurements that are taken at the start and then repeated twice more will be stored securely in locked filing cabinets at the University. They will be coded so that we can remove names, but we need to keep a record of the codes to compare each child's measurements / scores. We will present this information together for all of the children, but there will be no description that would identify individuals. We don't intend to talk to all families (that would take too long), but if you are invited to have the family discussion with us, we will also remove any description of you, your family, where you live, and so on. You will not be identifiable in this part of the work either.

We will present a report to the Somerset Activity and Sports Partnership, and might also write research papers for publication (in journals like *Managing Leisure* and *Pediatric Exercise Science*).

Are there any benefits from taking part?
Yes, you will receive a family health MOT. Your child will learn about exercise and physical fitness, and will also be given healthy breakfasts three times each week while they are involved in the DASH programme. There is no cost to you for any of this.

What happens next?
With this letter you'll find an information sheet for your child. There are also two forms to complete. The first is for you to give permission for your child to be involved in the DASH programme. The second is a different form for your child to complete to confirm that s/he is willing to take part. If you are willing for your child to participate, and s/he is too, these forms should be completed when the school nurse makes the first visit.

How we protect your privacy:
As you can see, everyone working on the study will respect your privacy. We have taken very careful steps to make sure that you cannot be identified from any of the information that we have about you.

All the information about you and your child will be stored securely away from the consent and assent forms. At the end of the evaluation study we will destroy the information we have gathered about you and your child. We will only keep the consent and assent forms with your name and address. We keep these for ten years because we are required to do so by the University.

Further information
If you have any questions about the research or how we intend to conduct the study, please contact us.

Title, name and role
☎ 02920 ******
✉ **********@cardiffmet.ac.uk

UREC reference number: XXXXXX

Title of Project: Do Activity, Stay Healthy - Evaluation

Child Information Sheet

Welcome to DASH!
DASH is a project that is about helping children become more healthy. It's partly about taking more exercise and getting fitter, and partly about eating healthy food. We want to find out if DASH is working, so we want to find out two things:
1. whether DASH works for you – we want to start this very soon;
2. what some families think about DASH – we want to do this at the end.

Why you?
You are being asked because we think you might be someone who could learn a lot about exercise and healthy eating if you take part.

What will happen?
DASH lasts for six months. At the very start a nurse will come to your house to see how tall you are, how heavy you are and take your waist measurement. After that you start the early morning DASH club where you do some exercise and have a healthy breakfast. This happens three times a week. One of the first things you'll do there is a bleep test where you run around until you want to stop – it doesn't last very long. After six weeks the nurse will take your measurements once more, and again after six months. You'll do the bleep test twice more as well.

After you've done this, we might ask you and your family to talk to us altogether about what you think of DASH.

Do I have to?
No, you don't. No-one is forcing you. And if you start and decide you don't want to carry on, that's fine. There's no problem, just tell us.

What do we do?
When we've got our information we will write a report for the people who pay for DASH. We might also write something for a book or a magazine. If we do this, we won't say who took part. No-one will know it's you or your family.

Have you got any questions?
If you have any questions just ask. You can ask us yourself, or you can get your parent or guardian to ask us.

Title, name and role
☎ 02920 ******
✉ **********@cardiffmet.ac.uk

Exemplar Consent Form

(Form to be on headed paper)

PARTICIPANT CONSENT FORM

Reference Number:
Participant name or Study ID Number:
Title of Project:
Name of Researcher:

Participant to complete this section: **Please initial each box.**

1. I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐

1. I agree to take part in the above study. ☐

The following statements could also be included on the consent form if appropriate:

2. I agree to the interview / focus group / consultation being audio recorded ☐

3. I agree to the interview / focus group / consultation being video recorded ☐

4. I agree to the use of anonymised quotes in publications ☐

_____ _____

Signature of Participant Date

_____ _____

Name of person taking consent Date

_____

Signature of person taking consent

** When completed, 1 copy for participant & 1 copy for researcher site file*