# CARDIFF METROPOLITAN UNIVERSITY CARDIFF SCHOOL OF SPORT AND HEALTH SCIENCES ETHICS FRAMEWORK

#### 1. Introduction

This document outlines the School Ethical Framework for the conduct of learning, teaching, research, innovation and enterprise by staff and students. This framework relates specifically to the School of Sport and Health Sciences but is aligned with institution-wide procedures approved by the <u>University Ethics Committee (UEC)</u>. The formal UEC terms and conditions for School ethics committees are presented in **Appendix I**.

This framework aims to protect the rights, dignity, health, safety and privacy of staff, students and participants in research and/or enterprise projects. The School also aims to protect the academic freedom of staff and students along with the reputation of the School as a centre for high quality learning, teaching, research, innovation and enterprise.

The policy set out here applies to all academic staff, postgraduate and undergraduate students when they plan to undertake internal or external research, innovative or enterprise projects and/or certain teaching exercises, and is based on the following ethical principles:

- **Non-maleficence**. Minimise harm to participants, researchers, institution & environment.
- Beneficence. Demonstrate potential for human benefit.
- **Dignity** and **autonomy** of participants.
- **Confidentiality** and **anonymity** of participants, where possible.
- Impartiality of researchers, where possible.
- Legal compliance with UK voluntary and statutory regulation.
- Non-discriminatory values and practices.

Studies may also be required to comply with externally developed guidelines, such as in the case of research/enterprise funded by Research Councils (e.g. BBSRC, Arts and Humanities Research, Economic and Social Research Council), Professional Bodies (e.g. British Psychological Society, BASES), Charities (e.g. AMRC, British Heart Foundation, Medical Research Council) or EU framework programmes.

Applicants are responsible for ensuring that they meet the requirements of external agencies. For links to professional and research council codes of practice applicable to research in the Cardiff School of Sport and Health Sciences (CSSHS) please refer to **Appendix II**.

### 2. CSSHS Ethics Structure and Decision Process

The ethics management structure is presented below in **Figure 1**. The School of Sport and Health Sciences Ethics Committee (SSHSEC) is responsible for ensuring that all research, innovation, enterprise and student projects carried out by staff and students conforms to ethical standards set by the School and approved by UEC.

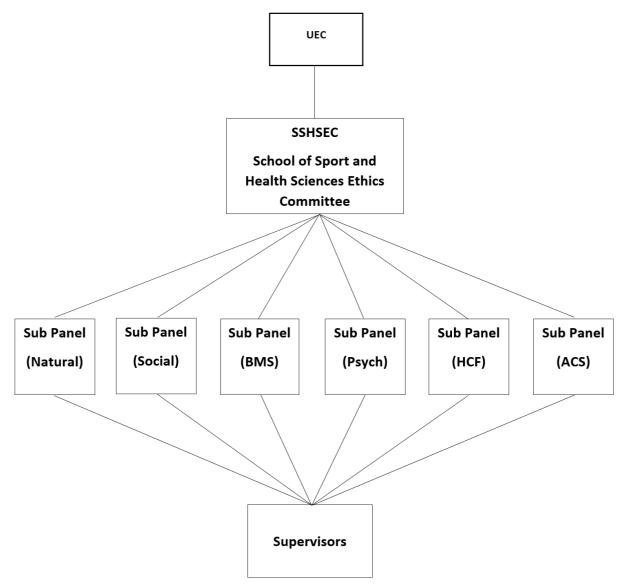


Figure 1. Ethics Structure for CSSHS.

BMS – Biomedical Sciences; HCF – Health Care & Food; ACS – Applied Community Sciences

SSHSEC devolves the assessment of all ethics applications to one of six ethics sub-panels or the supervisor of the project, depending on the subject matter. The decision process is dictated by a number of factors – these are outlined in **Appendix III**.

SSHSEC is also responsible for undertaking the audit of ethical decision making by the panels on an annual basis.

Unless the project involves contentious subject matter then the below can be signed off at Supervisor level:

- Undergraduate
- Postgraduate Taught (including Master of Research)
- Human Studies

All other applications, and those involving contentious\* project content, will need to be considered by the appropriate ethics panel and, if necessary, referred to SSHSEC. This will include:

- All Postgraduate research students
- All staff projects
- All Franchise based projects (UG, PGT and Research)

\*A contentious project refers to any of the following (see also checklist in **Appendix IV**):

- Human Participants clinical intervention.
- Human Participants administering of substances (e.g. drugs, placebos, vitamins).
- Human Participants prolonged or repetitive testing OTHER THAN repetitive training exercises of a type which may form part of a participants normal activities.
- Human Participants sensitive research where a topic area deals with sensitive aspects of participant behaviour.
- Human Participants patients (NHS or private) or vulnerable populations and/or participants who are unable to give informed consent.
- Projects involving children (<18 years old).</li>
- All projects involving sampling and/or storage of Human Material.
- Projects involving animals or sampling and/or storage of animal material as defined by the University Policy on working with animals see <u>UEC Policy on Work Involving Animals</u>.
- Projects involving PREVENT (e.g. any form of radicalisation see the <u>Cardiff Met Website</u> for further information).
- Project with the potential to cause reputational harm to the School/University.

**Note:** For applications involving PREVENT or animals, approval can be given at SSHSEC level, in conjunction with UEC's approval of the project.

# 3. Activities Requiring Ethical Approval

The following activities require ethical approval before any data collection can commence; this includes participant recruitment and sample procurement:

- a) All undergraduate and postgraduate dissertation/project work
- b) Postgraduate Research
- c) Staff-led research
- d) Innovation/Enterprise projects
- e) Certain teaching activities. Examples of teaching activities that may require ethical consideration are listed in **Appendix V**

For activities conducted externally by staff or students the route to ethical approval depends upon the arrangements at the institution where the Principal Investigator (PI) resides (provided that these are at least equivalent to Cardiff Met arrangements). If the PI is at Cardiff Met, they should apply through the internal School process. If the PI is at an external institution, they should gain formal ethical approval from that institution.

Ethical approval from another institution does not remove the responsibility of researchers to comply with the policies laid down by UEC. The Cardiff Met collaborator should provide evidence that the project has received ethical scrutiny and approval for all work undertaken. See also **section 6 below for information with regards to Health, Safety and Risk**.

If data is to be collected in an organisation external to Cardiff Met, written evidence that the member of staff or student has sought such permission must be provided to the School with the application for ethical approval.

Where researchers from external organisations wish to sample the School staff and/or student population for their research, an approved ethics application should be submitted to the Chair of the SSHSEC for review prior to any contact with the desired sample.

For details on informed consent working with children please see the <u>Cardiff Metropolitan</u> <u>University Guidance Notes</u> for completing an ethics application.

# 4. How to Apply for Ethical Approval

Ethics guidance and application forms can be found via the <u>Research and Innovation Services</u> unit. Staff can access the <u>CSSHS Ethics Homepage</u> for submission of applications, as well as links for panel member restricted access.

# 4.1 Undergraduate / PGT applications

New applications will be submitted to a supervisor for checking. If the project subject matter is non-contentious (see **appendix III / IV**) the supervisor is able to sign off the application as approved. The same applies for amendment applications, and the original ethical approval ID will be preserved for continuity.

If the supervisor has any concerns about an application prior to submittal they are able to contact a member of the relevant panel for guidance. It is recommended that if a supervisor has doubts about any element of a project, is a new member of staff, is new to the process, or has particular questions, the application should be referred to a panel.

# 4.2 Research / Staff / Enterprise

New applications will be submitted directly to the School for the attention of the required panel (research student applications must be submitted by their supervisor). The same applies for amendment applications, and the original ethical approval ID will be preserved for continuity.

The Panel/Committee has the ability to approve, not approve or reject applications submitted.

#### 4.3 Protocols

Under the existing UEC framework, School ethics committees can also consider applications for protocol approval. Protocols are standard procedures which may be used in a variety of contexts. The purpose of protocol approval is to set standards for these procedures across Cardiff Met, and to allow approval of projects which include an approved protocol. Where approved by Panels, protocols must be notified to SSHSEC for information. Refer to Cardiff Met <a href="Protocol Approval">Protocol Approval</a> for further guidance.

New applications can be submitted directly to the School for the attention of the required panel. The same applies for amendment applications, and the original Protocol ID will be preserved for continuity.

The Panel/Committee has the ability to approve, not approve or reject applications submitted.

# 5. Decisions Made by Panels and Committee

The current forms for ethical applications are drafted for institution-wide use and indicate in the decisions section that projects can be approved, approved in principle, deferred, not approved or rejected. CSSHS has refined the decision options and the supervisors, panels or SSHSEC will make one of the following decisions for each considered application (see list of Standard Ethics Email responses in **Appendix VI**):

- a) Approve
- b) Not approved (where the application is returned for revision)
- c) Reject (where the project is unethical)

In addition a Panel may also use the option "Defer to SSHSEC" where it feels unable to form an opinion as to whether the application is (or can be made) ethically sound.

Ethical approval, where granted, will normally be for a 12 month period from date of approval. It is the responsibility of the applicant (PI) to abide by the conditions of approval; this includes application for extension of approval. Approval may be granted for periods of up to 5 years in circumstances where projects are designed to last longer or where their implementation depends on securing funding from recognised organisations such as Research Councils UK (RCUK), the European Commission, or members of the AMRC.

It should be noted that although this document and the corresponding institutional forms for ethics application refer to ethical approval, the approval granted either by a supervisor, panel or by SSHSEC reflects the expression of a favourable ethical opinion made on the basis of the information provided by the applicant. Staff and students in the School should not proceed with projects if during the course of their conduct they come across circumstances that might suggest the basis for ethical approval has changed significantly and may require further ethical consideration. If after receiving approval investigators become concerned about the ethics of their activities they should contact the chair of the panel or committee that granted approval in the first instance for further guidance.

Full minutes of each Panel meeting will be provided to SSHSEC after initial approval by the chair, and in time for each SSHSEC meeting.

Panels will meet weekly/fortnightly depending on the volume of applications. To be quorate, panel meetings must include minimum of Chair plus 50% of members. Emeetings will not be allowed unless given approval by the Chair of SSHSEC. However, during July and August an e-meeting can replace the panel meeting and panel chairs should take on board the views of at least 2 other panel members.

SSHSEC will take place quarterly, and preferably a week before UEC in the event of an application needing to be referred on.

# 6. Health, Safety and Risk Assessment

The Health and Safety aspects of activities requiring ethical consideration are covered by the School Health and Safety Policy. It is also a requirement for applicants to assess risk in the context of ethics and to complete the relevant Risk Assessment documents. Risk assessments must be provided to the committee or panel on request but are not routinely required as accompanying documents for ethics applications.

Further information on the University <u>Health & Safety Policy</u> and <u>Guidance on</u> Risk Assessment can be found on the Staff Portal.

# 7. Activities Involving Human Participants

Activities involving human participants are defined as those that:

- a) directly involve people in the research/innovation/enterprise/teaching activities, through their physical participation. Physical participation may be invasive (e.g. taking of blood or other human materials) and/or non-invasive (e.g. laboratory-based experiments, interviews, questionnaires, surveys, observational, practical sessions) and may include the active or passive involvement of a person (passive refers to the use of secondary data about an individual);
- b) indirectly involve people in the research/enterprise/teaching activities, through their provision of, or access to, personal data or human materials;
- c) involve people acting on behalf of others (e.g. parents/legal guardians/carers of children and the psychologically and/or physically impaired, and supervisors of people in controlled environments e.g. pupils, psychiatric patients, prisoners).

The following principles apply to research specifically involving the administration of supplements to human participants:

- Only manufacturer recommended dosages are permitted unless there is explicit
  justification and support for higher dosages. Specific details in any instance need to be
  included in the application for ethical approval.
- Supplements must be purchased by a CSSHS technician from an approved supplier.
- For UG projects the discipline area may have some money to purchase supplements however students must be made aware that they may be liable for any additional costs for supplements.
- The supplements that are being administered must be available to the general public to ensure appropriate selection of recognized products.
- For UG and PG projects any measurement and mixing of the supplement must be completed by an authorised CSSHS member of staff.
- Unless there is explicit justification and support for longer exposure, supplementation must be acute (over a short period of time).

#### 8. Human Materials

At Cardiff Met, human materials are defined as all material derived from a human (cellular and acellular) that may be acquired, stored and used, including cell lines. The procurement, storage, handling, transfer, transportation and disposal of human materials must comply with the Policies and Procedures as set out in the University's <a href="Human Samples Quality">Human Samples Quality</a> <a href="Management System">Management System</a>.

# 9. Research Requiring Third Party Research Ethics Committee Approval

SSHSEC will not endorse research or projects that require approval from a nationally recognised Research Ethics Committee (REC) until such approval has been granted. In all cases a copy of the relevant REC favourable ethical opinion must be submitted to the School for consideration. Where a PI on the REC-approved research is not from Cardiff Met, evidence supporting the role of Cardiff Met in the project must also be provided.

For projects involving the NHS, REC approval must be obtained via the Integrated Research Application System (IRAS) which is managed by the NHS Health Research Authority (HRA).

HRA review is required for any research protocol involving:

- a) patients and users of the NHS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, the NHS. It includes NHS patients treated under contracts with private sector institutions;
- b) individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
- c) access to data, organs or other bodily material of past and present NHS patients;
- d) foetal material and IVF material involving NHS patients;
- e) the recently dead in NHS premises;
- f) the use of, or potential access to, NHS premises or facilities; and
- g) NHS staff recruited as research participants by virtue of their professional role.

Where an appropriate NHS Unit has decided that proposed activities do not require REC approval (e.g. service evaluations), a letter specifying exemption must be provided from the relevant unit (e.g. Research & Development Committee) together with the ethics application. See Exceptions and Other Exclusions in the GAFREC Guidelines.

These principles are also applied to research projects involving private hospitals and/or clinics (approval required by the specific institution's REC) as well as non-NHS patients in NHS facilities. Where the third party is a health care institution outside the UK, approval from a relevant recognised REC in that country will be required.

Other agencies may also have specific requirements for ethical approval (e.g., Ministry of Defence or Ministry of Justice). In these instances applicants must notify the relevant SSHSEC panel with evidence of written permission.

# 10. Appeals and Complaints Procedure

Applicants for Ethical Approval have the right of appeal against a decision. The process for such appeals and any complaints can be found in **Appendix VII**.

# 11. Audit of Approved Projects

SSHSEC will undertake a planned programme of annual audits of projects. Audit of projects will be an annual agenda item for SSHSEC and will entail sampling 10% of submitted projects. Quality of panel decision making will be assessed by consideration of the decisions made.

An audit of projects approved at supervisor sign off level will also be undertaken by the panels using random selection of projects held by each supervisor. Audits will be used to improve the ethics process and to inform staff development activities.

# 12. Composition of panels

Membership of the six panels is presented in **Appendix VIII**. Each Panel will also have a member from an alternative panel to serve in a voluntary capacity for a 6 month period at a time. This will provide an independent, non-specialist perspective and encourage consistency across panels. This will be arranged by SSHSEC.

# 13. GDPR Compliance

It is the responsibility of the Principal Investigator to ensure the project aligns with Cardiff Metropolitan University's policies and procedures regarding GDPR compliance. For further information please click here.

### 14. Contact Details

Mrs Katy Burson (Health Panels)
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Cardiff School of Sport & Health Sciences
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Telephone: +44 (0) 29 2041 7007
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# Appendix I

# School of Sport and Health Sciences Ethics Committee (SSHSEC) Formal terms of reference

SSHSEC will:

- 1. With the approval of UEC establish, implement, and keep under review procedures and guidelines for the consideration, approval, and monitoring of research, innovation, enterprise and teaching projects which are undertaken by members of staff and/or student members of the School; this includes the setting up of sub-panels to consider applications for approval from designated parts of the School.
- 2. Ensure projects involving human participants, samples derived from human material, animals, or projects with potential to cause reputational harm to the University, are carefully considered and ethically undertaken.
- 3. Ensure that ethical principles are clearly laid down and are disseminated to staff and students of the School, and that ethical practices are adhered to.
- 4. Ensure that appropriate training in ethics is put in place for members of the School undertaking or supervising research involving human participants.
- 5. Keep the School's Ethics Guidelines under annual review.
- 6. Report annually to UEC on the numbers and types of projects considered by the committee, together with details of any policy or procedural changes recommended by the committee.

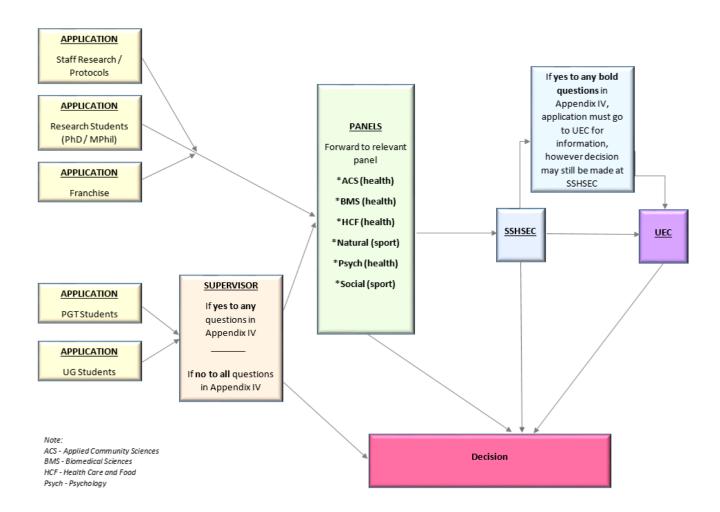
# **Appendix II**

# **Links to Useful Ethics Guidelines**

<b>BASES</b>	BBSRC	BERA	British Psychological Society	
British Sociological Association	<b>ESRC</b>	<u>GAFREC</u>	<u>HCRW</u>	
<u>HRA</u>	Human <u>Tissue</u> Authority	Human Tissue Authority (Relevant Materials)	<u>IRAS</u>	
MRC	National Children's Bureau	National Offender  Management  Service	<u>NERC</u>	
	<u>UKRI</u>	<u>UUK</u> <u>Concordat</u>		

# **Appendix III**

# **Application Decision Process**



# **Appendix IV**

# Checklist for supervisors to assess whether an application requires panel approval.

Will the study involve animals?		
Will the study involve children?*	Yes	No
Will the study involve vulnerable populations and/or participants who are unable to give informed consent?		
Will the study involve working with NHS patients?	Yes	No
Will the project involve human materials?**	Yes	No
Will the project involve clinical intervention?	Yes	No
Are drugs, placebos, or other substances (e.g. vitamins) to be administered to participants?	Yes	No
Will the study involve prolonged or repetitive testing OTHER THAN repetitive training exercises of a type which form part of the participants normal activities (e.g. athletics or music training)?		
Will the study involve sensitive research where a topic area deals with sensitive aspects of participant behaviour?	Yes	No
Will financial inducements, other than reasonable expenses and compensation of time, be offered to participants?		No
Will the study involve deceptive research where an investigator actively sets out to significantly misinterpret himself/herself, the nature of the research, and/or any other significant characteristics of the research?		No
Will the study involve work concerning prevention, e.g. terrorism?		
Does the study have the potential to cause reputational harm to the University?		

### **Notes:**

If Yes to questions in bold, application must be referred to SSHSEC via Panel.

If Yes to ANY question listed, application to be referred to Panel.

<sup>\*</sup> Projects in professional practice involving groups of children in a public place in school, with the schools' permission, are exempt.

<sup>\*\*</sup> Human Materials - further information

# Appendix V

# Definitions and examples of teaching activities that may require ethical approval

The following list is not intended to be exhaustive and if you are in any doubt, please contact the Chair of your relevant Ethics Panel for advice.

Please note that this list does NOT mention taught undergraduate or postgraduate projects or dissertations. These ALWAYS require ethical approval at either supervisor or panel level as appropriate.

Teaching activity that DOES require ethical approval:

- Activity that involves use of human materials (procured outside the University), including those deemed not relevant under local Human Tissue Codes of Practice.
- ii. Activity that involves use of human materials (procured as part of the teaching activity), including those deemed not relevant under local Human Tissue Codes of Practice.
- iii. Activity where drugs, placebos or other substances (with the exception of retail food items) are administered to participants.
- iv. Activity that could induce physiological or psychological stress.
- v. Activity that involves participants under the age of 18 years.
- vi. Activity that involves participants who have limited capacity to give informed consent by virtue of mental illness or intellectual/learning disability.
- vii. Activity that might involve a serious Health and Safety risk.

Teaching activity that MAY require ethical approval:

- viii. Activity where non-retail food samples are administered to participants.
  - ix. Activity where physical exercise may induce physiological stress in some individuals.

Teaching activity that DOES NOT require ethical approval:

- x. Paper based activity, only including documents in the public domain.
- xi. Laboratory based, not involving human participants or human materials.
- xii. Activity where anonymised data are collected from students by questionnaire for the purposes of data collection for internal teaching, observing and reporting on professional practice, or statistical analysis methods only.

The School will not generally give approval for teaching activity that involves participants unable to give informed consent or requests for covert activity or deception of participants in a teaching context.

# **Appendix VI**

# **CARDIFF SCHOOL OF HEALTH SCIENCES**

### **Standard Ethics Emails**

- 1. Approved incorporating a paragraph for any VERY minor special conditions.
- 2. Not Approved incorporating a list of required amendments
- 3. Rejected
- 4. Amendment Approved
- 5. Amendment Not Approved incorporating a list of required amendments
- 6. Amendment Rejected
- 7. PROTOCOL Approved
- 8. PROTOCOL Not Approved incorporating a list of required amendments
- 9. PROTOCOL Rejected

# Appendix VII

# **Appeals Procedure**

# 1. Appeals against Panel Decisions

Where an application has been rejected by a Panel, the applicant (or supervisor if the applicant is a student) has the right to request that the decision is reconsidered by the relevant Panel. Appeals should be made to the Chair of the Panel in the first instance via the Research and Enterprise Support Manager, setting out the cause(s) for concern. This communication should contain sufficient information to allow the grounds for appeal to be clearly understood. If the Panel revokes its original decision, the appeal can be upheld without a hearing.

If that Panel affirms its original decision, the applicant has the right to appeal to SSHSEC in which case the appeal will be received by SSHSEC as written. SSHSEC will then convene a hearing and invite the applicant to meet with them. If additional expertise is required, the Chair may invite up to two members of staff with relevant expertise but who have not been involved in the initial decision to join the panel. After the hearing, SSHSEC will determine whether the applicant is successful. It is the duty of the Ethics Appeal Panel to provide clear justification for its decision regarding whether an appeal has been successful or unsuccessful.

The Panel must consider any written appeal within 10 working days and SSHSEC within 20 working days. All appeals must be made within 2 months of the original decision being relayed to the applicant/supervisor.

# 2. Appeals against SSHSEC Decisions

Where an application has been rejected by SSHSEC, the applicant (or supervisor if the applicant is a student) has the right to request that the decision is reconsidered by the Committee. Appeals should be made to the Chair of SSHSEC via the Research and Enterprise Support Manager, setting out the cause(s) for concern. This communication should contain sufficient information to allow the grounds for appeal to be clearly understood. If the SSHSEC revokes its original decision, the appeal can be upheld without a hearing.

If SSHSEC affirms its original decision, the applicant has the right to appeal to UEC in which case the appeal will be forwarded by SSHSEC to the Chair of UEC with the justification for its decision.

SSHSEC must consider any written appeal within 20 working days. Appeals must be made within 2 months of the original decision being relayed to the applicant.

### 3. Complaints

Complaints against SSHSEC or the School Panels should be made following the University published complaints procedure

# Appendix VIII

# **Sport and Health Sciences Ethics Panel Membership**

Chair	Rachel Lord	Harry Bowles	Rachel Adams	Nick Perham	Arthur Tatham	George Karani
Vice-Chair			Keith Morris	Andy Watt	Judith Whatley	Andy Curnin
Member	Mike Stembridge	Neil Hennessy	Amanda Davies	Sarah Taylor-Jones	Rhiannon Harris	Mel Jones
Member	Rhodri Lloyd	Lisa Edwards	Maninder Ahluwalia	Mike Dunn	Robert Mayr	Val Scholey
Member	Izzy Moore	Andrew Lane	Barry McDonnell	Mirain Rhys	Ruth Fairchild	
Member	Peter O'Donoghue	George Jennings	Claire Kelly		Jane Lewis	
Member	Andrew Miles		Mike Beeton			
Member						
Alternate						
Member						
Alternate						
Member						
Ethics	Donna O'Flaherty/	Donna O'Flaherty/	Katy Burson	Katy Burson	Katy Burson	Katy Burson
Support	Huw Jones	Huw Jones				