

**UNIVERSITY OF STRATHCLYDE  
UNIVERSITY ETHICS COMMITTEE**

**ANNUAL REPORT TO UMC FOR 2008/09**

**EXECUTIVE SUMMARY**

The University Ethics Committee (UEC), with its associated Departmental Ethics Committees, has been established to consider general ethical issues relating to the teaching and research of the University which involve investigations on human beings. It aims to provide impartial advice to participants and investigators and to protect the dignity, rights, safety and well-being of all actual and potential participants. In carrying out this role, the UEC is the body responsible for giving ethical approval for investigations. Ethical approval is required before any such investigation can start.

This paper represents the annual report to UMC from the University Ethics Committee for the period 2008/09. Information on policy development, approval of applications, monitoring of projects, training, internal and external challenges and risk management is provided in the document and associated annexes.

UMC is asked to:

- i. Consider and comment on this annual report from the University Ethics Committee
- ii. Consider UEC's request for delegated authority to make amendments to the Code of Practice.

## **PROGRESS AGAINST TARGETS**

2. The University Ethics Committee (UEC) does not have specific targets, but there are a number of areas of activity which are essential to the effective and efficient operation of the Committee and which are closely monitored. These include:

### **Policy Development**

3. The UEC developed and significantly revised the Code of Practice, approved by Court in March 2008, to ensure that it remained user-friendly and accessible, to reflect changes externally and to clarify and streamline procedures. The Code of Practice is accessible via the UEC web page (<http://www.strath.ac.uk/secretariat/ethics/>) and is now being used by researchers across the University. Members of UEC have been active in ensuring that the Code of Practice is followed and associated training has been delivered to academic staff. The procedures outlined in the Code of Practice signify efficiencies in the application processes by devolving a greater number of low risk projects to Departmental Ethics Committees (DECs).
4. For the Code of Practice to remain relevant and useful to researchers, it is essential that there is scope to revise guidance to reflect developments in the external environment. During the course of the year, the UEC has issued a number of updates, which have been displayed on the web page and communicated to researchers directly. Such revisions and clarifications include: guidance for research in Scotland involving children under 12; data guidelines, focused on data storage and security; differing legal requirements between Scotland and England in relation to informed consent and the age of maturity; endorsing ethical approval granted by NGOs to collaborative projects (provided that the UEC has considered the associated ethical process); and revealing information to the authorities. These amendments reflect the reality of the speed of change in the legislative and research environment and will be included in the next full-scale revision of the Code of Practice, likely to be published in early 2010, which will seek to consolidate the amendments.
5. A substantial amount of the research involving human beings is governed by NHS ethical processes and the UEC pays close attention to any developments in this area. Over the past year, these have included clarification of the chief investigators in NHS ethics applications and model agreements to be used for non-commercial research. Most recently, there have been significant revisions to the NHS process for ethical approval and UEC members have been closely involved in training sessions operated at the University. The policy of the NHS Ethics Committees taking priority, with applications considered by the Convener of the UEC on behalf of the Committee once NHS approval has been received, has been operating effectively during the past year.
6. The UEC is also keen to develop internal practices, to ensure that processes are effective and efficient and to share best practice across the University community. As such a database has been established to monitor and record applications and track data trends over the past few years. This has been coupled with a close examination of the application procedure and developments are currently being implemented.

### **Approval of Applications**

7. The UEC considered a total of 70 applications during 2007/08, of which 61 were approved. The remaining 9 were either withdrawn, did not require ethical approval or have amendments which are outstanding. This total compares with 50 during the previous session (2006/07). To date, during 2008/09, a total of 51 applications have been considered, of which 6 have decisions outstanding, pending amendments. A number of the approvals during 2007/08 and 2008/09 have been related to NHS applications or have involved generic approvals or requests for devolvement of responsibility to DECs. Summaries of applications considered and approved by the UEC are available on request to the secretary to UEC.

### **Monitoring of Projects**

8. The UEC monitors the progress of each of the applications which is approved, either directly with the chief researcher of each project or via the relevant Departmental Ethics Committee (for generic or devolved applications). This monitoring takes place in July/ August each year. The UEC is currently monitoring 124 projects.

### **Monitoring of Departmental Ethics Committees**

9. The UEC also monitors the activities of all the Departmental Ethics Committees, on an annual basis. The DECs are required to provide an annual report to the UEC each spring, summarising the progress with individual applications and providing a formal opportunity to raise pertinent issues with the UEC.

This allows the UEC to keep abreast of any concerns that DEC's and staff within departments may have. To date, 16 DEC's have provided information about the activity of their Committee, 7 departments do not have DEC's and the reports are being followed up with the remaining 14 DEC's.

## **CHALLENGES AND FUTURE ISSUES**

### **Ethics Training and Education**

10. The University Ethics Committee established a sub committee in autumn 2008, to consider the provision of ethics training within the University, to develop a strategy for ethics training and to design and implement appropriate ethics training modules and awareness-raising events. The sub committee is chaired by Dr Niamh NicDaeid, who is currently serving as a Vice-Convener to the main Committee, and is comprised of the Convener and members of the UEC along with representatives from Research & Innovation, the Secretariat and CAPLE.
11. To date, consultations about training provision have been carried out with Departmental Ethics Committees and active researchers and the results of these consultations have informed the development of a generic training package, which is currently being finalised. Future work will include developing training material for specific ethics-related issues, including: data protection, anonymity and confidentiality; Consent forms and Participation Information Sheets; risk assessment; developing generic applications; and ethical issues relating to vulnerable participants. An ethics reading group has been established, enabling staff to meet research colleagues from across the University and to discuss current ethics-related issues. Chairs of DEC's have also been invited to attend UEC meetings, to help raise awareness and knowledge of the ethics processes. So far, members from 4 DEC's have attended a UEC meeting and the invitation remains open to enable further colleagues to attend in the future.

### **External Environment**

12. It is essential that staff conducting investigations involving human participants keep abreast of relevant developments in the external environment, whether they be legislative requirements, changes in the NHS procedures or professional standards and the Code of Practice places clear responsibility on the Chief Investigator of each research project to ensure that the investigation is conducted in accordance with those external requirements (see Code of Practice, Annex 4). However, the UEC takes seriously its role to keep informed about external developments and takes steps to ensure that this is carried out.
13. The University is a member of the Association of Research Ethics Committees (AREC) and its sub committee, the University Research Ethics Committee (UREC) and UEC members participate in and receive regular information from these bodies. The UEC is comprised of members from across the five faculties of the University and has external and lay members with legal, medical and ethical expertise and, in this way, shares information about developments in professional practice and the external environment more generally. Close links with the NHS are also maintained, through research-active members of the Committee, through colleagues in Research & Innovation and through regular attendance at the Glasgow Research Governance Group. Such external awareness will continue to be of central importance in the future and will form a key part of the development of training provision.

### **Internal Developments**

14. The UEC has identified the need to develop a definitive electronic version of the Code of Practice and related application forms that can be published online, to enable amendments in response to changing legislation and case law to be made in a timely fashion. The UEC is seeking delegated authority to make such amendments to the Code of Practice. Adequate IT support will also be required to develop this resource.
15. In keeping with the guiding principles of the Professional Services Review, the UEC seeks to develop and maintain a streamlined approach to the ethics applications procedures, which balances the legislative, ethical and governance requirements with the needs of active researchers. Administrative staff supporting the UEC are currently looking in detail at these procedures, with the objective of making the system more effective, efficient and transparent. Discussions are also ongoing with colleagues in ITS to explore the potential of an electronic application system in conjunction with the development of the Research Information Management System.
16. The outcomes of the ongoing reviews of Professional Services and Decision-Making Structures and Processes are likely to have an impact on the work of the UEC and new processes will be flexible to respond to the implementation of recommendations. The UEC is keen to balance strategic developments with the detailed consideration of medium and high risk projects.

## **UNIVERSITY ETHICS COMMITTEE MEMBERSHIP**

17. The UEC has confirmed that Mrs Condie will continue as Convener for a further three years. This extension will enable the UEC to continue to benefit from the experience Mrs Condie has built up during her time on the Committee. There are currently three Vice Conveners supporting the work of the UEC, a system which has now been in place for a year and has proven to be very effective. The wider membership of the UEC is currently being reviewed ahead of the next session and, at their last meeting, the UEC agreed to seek a new member from the Glasgow School of Social Work or the Counselling Unit, to replace Mr Hosie, who is coming to the end of his period of membership. The current membership of the UEC is included as annex 1.

## **RISK MANAGEMENT**

18. The UEC takes risk management very seriously and risk assessment is a constant part of its work, as members evaluate potential risks to human participants and the potential benefit of the research in their consideration of each application. Individual risk assessments for each ethics application are carried out by colleagues in Research & Innovation, who also confirm the University's appetite for sponsoring each project, and an associated member of staff attends the UEC meetings. Furthermore, a representative from Finance is also in attendance at each UEC meeting and this representative liaises with the University insurers to establish sufficient cover for each application. Researchers are not approved to commence their work until all aspects of this process have been confirmed.

19. A risk register is attached as annex 2, which represents the typical process of consideration of applications by the UEC. The UEC will take ownership of the risks identified on the risk register and will further consider whether individual owners should be assigned. The UEC is also considering the optimum times to review the risk register and it is likely that this will take place on a biannual basis, commencing in the 2009/10 session.

## **NEXT STEPS**

20. UMC is asked to:

- i. Consider and comment on this annual report from the University Ethics Committee, as necessary
- ii. Consider UEC's request for delegated authority to make amendments to the Code of Practice.

JE, on behalf of UEC  
May 2009

**UNIVERSITY ETHICS COMMITTEE  
ANNEX ONE: UEC MEMBERSHIP 2008/09**

<b>Name</b>	<b>Category/Faculty</b>	<b>Appointed</b>	<b>Membership ends</b>
<b>Convener</b>			
Ms E Condie	National Centre for Prosthetics and Orthotics	01.09.03	31.07.09*
<b>Internal Members</b>			
Dr A Agapiou	Architecture	01.08.06	31.07.09*
Professor J Blackie	Law School	01.05.05	31.07.11
Dr C Burns	HRM	01.08.08	31.07.11
Prof D Christie	Childhood & Primary Studies	01.09.05	31.07.11
Mr A Hosie	Social Work	01.09.03	31.07.09
Dr J Johnston	SIPBS	01.03.08	31.07.10
Dr S Kelly	Psychology	01.08.06	31.07.09*
Prof E Maclellan	Educational Studies	01.09.03	31.07.10
Dr N NicDaeid	Forensic Science	01.09.03	31.07.09*
Dr P Riches	Bioengineering	01.08.07	31.07.10
<b>External Members</b>			
Dr J Bunney	Chief Pharmacist (Retired)	01.11.04	31.07.10
Dr H Gray	Student Health Service Consultant, GRI (retired)	01.10.00	31.07.09*
<b>Lay Members</b>			
Mr D Blyth	Lay	01.11.06	31.07.09*
Mr C W Turner	Lay	01.10.04	31.07.10
Mrs M Whitehead	Lay	01.04.07	31.07.09*

\*Membership continuing for additional period

**University Ethics Committee  
Annex Two: Risk Register**

**ANNEX 2**

<b>Risk Nbr</b>	<b>Description of risk</b>	<b>Significant consequences</b>	<b>Key controls and mitigating factors</b>	<b>Early warning mechanisms</b>	<b>Likelihood (L/M/H)</b>	<b>Impact (L/M/H)</b>	<b>Owner</b>
1	Data issues	Researcher loses data; Data is corrupted; Anonymity of data is not preserved; University not compliant with Data Protection Act; Potential for litigation; Potential harm to participants; Potential damage to University reputation.	University has clear Data Protection Policy; Guidelines within ethics application relating to data storage and security have recently been updated; Data is required to be stored in secure location on University premises, wherever possible, or be encrypted and password protected; UEC considers data issues as standard aspect of all applications.	Feedback from researchers; Feedback from participants.	<b>M</b>	<b>H</b>	UEC
2	Potential harm to participants in project approved by UEC	Damage to physical/ mental wellbeing of participants; Resulting damage to reputation of University; Potential for litigation.	Ethical consideration of all medium-high risk projects by UEC focuses on well-being of participant above all other issues; Informed consent is one of guiding principles of UEC; Participants always encouraged to ask questions; Contact details of independent contact (usually secretary to UEC) provided on all information to participants; Regular monitoring of projects.	Negative feedback; Monitoring.	<b>L</b>	<b>H</b>	UEC
3	Negative outcome of project approved by UEC or a project carried out in unethical manner	External reputation of University affected - impact on staff and student recruitment and resulting impact on ability to attract funding and deliver strategic objectives; Possibility of legal ramifications.	UEC considers all projects that meet clearly defined criteria; UEC considers all medium and high risk projects in detail, drawing on extensive knowledge and experience of members; Risk management analysis carried out by R&I for all projects; Management approval considered for all projects by Director of R&I and Deputy Principal; Regular monitoring of projects and DEC's.	Negative feedback; Responses to monitoring.	<b>L</b>	<b>H</b>	UEC

**University Ethics Committee  
Annex Two: Risk Register**

<b>Risk Nbr</b>	<b>Description of risk</b>	<b>Significant consequences</b>	<b>Key controls and mitigating factors</b>	<b>Early warning mechanisms</b>	<b>Likelihood (L/M/H)</b>	<b>Impact (L/M/H)</b>	<b>Owner</b>
4	Failure of staff and students to follow University procedures	Projects carried out without appropriate ethical approval, University sponsorship or insurance; Harm to participants; Risk of litigation/ legal ramifications; Risk to external reputation of University - impacts ability to recruit staff and students and to attract funding.	Suitable training developed about relevant procedures - much greater focus on this since development of sub-committee; Code of Practice published on website; Updates to procedures are publicised widely; UEC web page is regularly updated; Regular reviews of suitability of all aspects of procedures; Any projects that require external funding are routed through R&I and staff can identify grant proposals that require ethical approval; Increased liaison with DECs to raise awareness; Applications are signed off by Chief Investigator and relevant Head of Department; Contact details for independent contact are included on all information to participants (usually the secretary to UEC); University sponsorship and insurance have to be in place before a project can start; Regular monitoring of all ongoing projects and of DECs; UEC has high-level administrative support, able to provide advice and guidance to researchers.	Negative feedback about research projects; Projects being submitted for external funding through R&I can be identified; UEC members drawn from across the research community within the University; Incomplete applications; Monitoring of projects and DECs.	L	H	UEC
5	Inadequate supervision for students undertaking projects within University or with external partners	Quality of application is not adequate - ie. methodology is not ethically sound, ethical issues are not adequately considered; Potential impact to participants; Potential damage to external reputation; Potential for litigation.	Chief Investigator (ordinance 16 staff) required for each project (only exception is NHS projects); Close liaison with CI in terms of UEC decisions and requests for amendments; Regular project monitoring ensures continuing supervision; UEC requires notification about changes to supervision; Development of training for supervisors; CIs and HoDs required to sign applications.	Incomplete/ unsigned applications; General quality of application; Monitoring.	L	H	UEC

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Annex Two: Risk Register**

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6	Failure of staff and students to follow external procedures and/ or meet external requirements	Projects carried out without appropriate ethical approval, sponsorship or insurance; Harm to participants; Risk of litigation/ legal ramifications; Risk to external reputation of University - impacts on ability to recruit staff and students and ability to attract funding; Research does not meet professional standards.	UEC requires that projects undertaken in collaboration with other universities receive ethical approval from university sponsoring the research, and applications are submitted to R&I and Finance to ensure adequate risk management/ sponsorship and insurance cover is in place before the project begins; UEC member of external organisations and groups (AREC/ UREC/ Glasgow Research Governance Group) to ensure it is informed about external developments; Training provided to staff and students about expectations in relation to external requirements/ procedures; Close liaison with key contacts in NHS; Any projects that require external funding are routed through R&I, and staff can identify grant proposals that require ethical approval; Increased liaison with DEC's to raise awareness.	UEC convener reviews ethical status of all external projects; Negative feedback about research projects; R&I work in relation to funding/ sponsorship.	L	H	UEC
7	Failure of UEC members to understand processes/ legislative requirements	Projects approved that are not ethically sound; Projects approved that do not meet legal requirements; Potential for legal ramifications and/ or litigation; Potential harm to participants; Damage to external reputation of University; Projects approved without appropriate insurance cover or sponsorship.	UEC members have a breadth and depth of experience from across range of relevant fields; New members are drawn from relevant areas of University, to ensure this level of expertise continues; Development of training for UEC, DEC and researchers across University; Quorum of 7 members required for each meeting; Code of Practice sets out procedures in clear and accessible way; UEC able to seek further external advice if decision is not clear.	UEC meetings	L	H	UEC



**University Ethics Committee  
Annex Two: Risk Register**

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8	UEC unable to reach decision on applications	Failure to reach a decision may impact on project, in terms of delayed start, opportunities for funding, etc; Ethical approval process undermined if UEC becomes known for inability to reach decision.	All medium-high risk projects are considered by the UEC at their regular meetings; Breadth and depth of experience means that members have expertise to reach decisions on wide range of issues; UEC will seek further advice from external experts if required.	All projects awaiting approval are reviewed at every meeting.	<b>L</b>	<b>M</b>	UEC
9	UEC fails to adequately monitor external environment	Decisions do not reflect changes to legal and/ or professional requirements; NHS applications may not be approved if correct advice is not provided.	Members with wide range of expertise ensures good awareness of legal and professional issues; UEC has membership of external bodies, including AREC, UREC and Glasgow Research Governance Group; Regular contact with NHS colleagues; UEC agenda has information sharing as standing item; Ethics Reading Group discusses current issues - information distributed to UEC; Training and awareness-raising sessions; Code of Practice outlines clear expectation for researchers to keep up to date with developments to professional standards and UEC will seek advice from researchers in field as required.	Feedback from researchers	<b>L</b>	<b>M</b>	UEC
10	Projects are not/ not adequately insured	Potential of legal ramifications/ litigation	Finance representative responsible for insurance is in attendance at each UEC meeting and reviews all subsequent amendments to applications; All UEC applications scrutinised for adequate insurance cover.	Insurer requires further details about applications.	<b>L</b>	<b>M</b>	UEC

**University Ethics Committee  
Annex Two: Risk Register**

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11	Failure of DEC members to understand processes/ legislative requirements	Projects approved that are not ethically sound; Projects approved that do not meet legal requirements; Potential for legal ramifications and/ or litigation; Potential harm to participants; Damage to external reputation of University; Projects approved without appropriate insurance cover or sponsorship.	DEC members are experts in relevant field and external or lay member is required; DEC often includes member of UEC; Code of Practice made widely available on website to all staff within University; Development of training programme; UEC professional support is able to provide advice and guidance as necessary; Regular monitoring of DEC's; DEC consider low risk projects only.	Response to regular monitoring; Feedback from researchers/ participants; Applications coming to UEC that could be dealt with at DEC level.	L	L	UEC
12	UEC lacks experienced staff/ suitably-wide membership	Judgements taken in relation to applications are not ethically sound; Judgements taken do not comply with legislative requirements; Decisions are inconsistent in relation to similar applications.	Convener/ Vice Conveners/ Members appointed on fixed-term basis; Period of membership is known for all members; Membership regularly reviewed and discussed by whole Committee and new appointments are sought from relevant areas; Lay and external members have skills/ expertise in relevant areas; Wide pool of potential internal members - from across research community; Awareness-raising via sub-committee for training and education, ethics reading group and website to further widen pool of potential internal members; Networks/ contact with external environment builds pool of potential external/ lay members.	Regular review of membership	L	L	UEC