UNIVERSITY OF STRATHCLYDE
UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR 2010

INTRODUCTION
The University Ethics Committee (UEC), together with its associated Departmental Ethics Committees (DEC), 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. The UEC is the body responsible for giving ethical approval for investigations. Ethical approval, together with insurance cover and sponsorship approval, must be in place before any such investigation can start.

This paper represents the annual report from the University Ethics Committee for the 2010 calendar year. Information on policy developments, approval of applications, monitoring of projects, training, internal and external challenges and risk management is provided in the paper and associated annexes. Research and Knowledge Exchange Services ("RKES") took over management of the UEC from Corporate Services as of February 2010 and is currently managed by Lynda Frew and Louise McKean with support from Carol Badger.

This paper will be considered by Research & Knowledge Exchange Committee.

PROGRESS AGAINST TARGETS

1. The 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 UEC and which are closely monitored. These include:

ONGOING ACTIVITIES

Code of Practice

2. The Code of Practice on Investigations Involving Human Beings was significantly revised in 2009. No revisions have been made in 2010 although the UEC and UEC Managers keep a record of new issues to be incorporated into the next revision of the Code of Practice, likely to be developed over the next 12 months.

Website

3. The UEC website continues to be regularly updated by the UEC Managers with advice (such as a new "Helpful Hints" section) and training opportunities. The UEC website is being used and prompted as an important source of information for staff and students. The UEC currently has a brief presence on the Researchers' Portal. The UEC plans to add more information to the Researchers' Portal based on the training materials developed by the UEC and RKES for the workshop entitled "Human Guinea Pigs".

Training

4. With support from researcher's development (Roberts funding) resources were allocated to develop training materials and deliver two one-day workshops aimed at career researchers and postgraduate students. The UEC Managers and at least four UEC members attended and facilitated at each workshop. Feedback from the workshops was very good. The training materials will be used in an annual workshop to be held by UEC members and the UEC Managers for early career researchers and post graduate students and for any other training provided by the UEC. The UEC will continue to provide ad hoc training upon request as well as developing 'Sharing Best Practice' sessions for Department Ethics Committee members and Academic Supervisors. Related to training, the UEC Managers have started a new 'drop-in' session to be held over lunchtime on the third Thursday of each month. Researchers will be able to obtain advice on ethics applications from an experienced UEC Manager without an appointment.

AREC Workshop

5. The UEC and UEC Managers played an important role as host and facilitator for the first Scottish workshop organised by the Association for Research Ethics Committee (AREC). The UEC and UEC Managers, in consultation with the NHS, organised the programme and speakers. 68 members of Scottish University and NHS ethics committees registered to attend the one day workshop held in the Collins rooms on 9 February 2011. UEC members presented during the day on various topics. Feedback from attendees was very good and the UEC intends to maintain an active role in organising and coordinating future such events. The UEC sought the assistance of the Principal in approaching Universities Scotland to ask for an ethics subcommittee to be formed. The University has continued its membership of AREC.

On-line UEC application process

6. The UEC and UEC Managers continue to discuss the development of an on-line ethics application process with Learning Services. The most recent advice form Learning Services suggests that such a process could be ready to be trialled over the summer.

HASS ethics procedure

7. Due to the structure in the new HASS Faculty the UEC Managers spent significant time with HASS administration considering the ethics and sponsorship procedure and assisting with the development of a new ethics approval process within HASS. The new procedure is available on the UEC website and the detail of the procedure will be further developed over time with experience. The new procedure which includes adoption of School Ethics Committees to fulfil the function of Department Ethics Committee will be incorporated into the revised Code of Practice.

Approval of Applications

8. The UEC considered a total of 38 applications in 2009/2010, of which 35 were approved. Out of the remaining 3, 1 was withdrawn and 2 were referred to the appropriate DEC. This total compares with 72 during the previous session (2008/ 2009). To date, during 2010/ 2011, a total of 33 applications have been considered, of which 9 have decisions outstanding, pending amendments, 1 application was withdrawn and 1 was declined. A number of the approvals during 2009/2010 and 2010/2011 have been related to NHS applications or have involved generic approvals or requests for devolvement of responsibility to DEC's. Summaries of applications considered and approved by the UEC are available on request to the Secretary to UEC ethics@strath.ac.uk.

Monitoring of Projects

9. The UEC monitors the progress of each of the applications which is approved, either directly with the chief investigator of each project or via the relevant DEC (for generic or devolved applications). The monitoring takes place in March/April each year. The UEC is currently monitoring 154 projects.

Monitoring of Departmental Ethics Committees

10. The UEC also monitors the activities of all the DECs, on an annual basis. The DEC are required to provide an annual report to the UEC each year summarising the progress with individual applications and providing a formal opportunity to raise relevant issues with the UEC. This allows the UEC to keep abreast of any concerns that DEC's and staff within departments may have.

The annual monitoring forms for the year January to December 2010 have recently been issued and the majority of Departments have completed and returned them. Following the restructuring of the HASS, the Departmental Ethics Committees for this faculty have been replaced with School Ethics Committees. This change came into effect in September 2010 and the Research and Knowledge Exchange Team (RaKET) have taken on the reporting responsibility and updated the annual monitoring returns accordingly.

To date, 26 DEC/SEC monitoring forms have been received. Any comments have been noted and acted upon where relevant. Any outstanding reports are being followed up.

CHALLENGES AND FUTURE ISSUES

11. The UEC and UEC Managers will continue to progress the activities described above and any new developments that arise during the next year. The UEC and UEC Managers aim to be as responsive and proactive as possible in this area within the University and the sector. However there is a limit to the resources available and an ongoing challenge for UEC members and managers as individuals is to meet the demands of the UEC

UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

12. The UEC has confirmed that Mrs Condie will continue as Convenor 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 in the UEC. It also ensures that researchers continue to receive a robust and prompt response to their research protocols. There are currently

four Vice-Convenors supporting the work of the UEC including long standing members and Vice-Convenors Steve Kelly and Niamh Nic Daeid and new Vice-Convenors Phil Riches and Douglas Blythe. The UEC sought new members from the Engineering Faculty and Business School. James Windmill from EEE joined the Committee in June 2010. The Business Faculty has yet to suggest a new member. Joanna McPake has responsibilities within the HASS Faculty ethics and sponsorship procedure and has attended UEC meetings to help increase her knowledge and experience of the UEC. The current membership of the UEC is included as annex 1.

13. The UEC has been well supported by Zoe Wilson from the Finance Office with respect to insurance for some years. With Zoe's departure from the University Aileen Stevenson will temporarily provide that support until a permanent replacement can be found.

RISK MANAGEMENT

14. 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 the Committee Managers, who also confirm if the University will sponsor each project. A representative from Finance is in attendance at each UEC meeting and this representative liaises with the University insurers to establish sufficient cover for each application. Researchers must not commence their work until all aspects of this process are confirmed. This is confirmed in all email contact with researchers.

15. A risk register is attached as annex 2.

BUDGET

16. The UEC has a running costs account with the budget currently standing at £10,969. The budget can be used by members to attend appropriate training events.

NEXT STEPS

17. A copy of this report will be provided to the UEC and once approved by the University will be posted on the Ethics web page.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP 2010/11

Name	Category/Faculty	Date Appointed	Membership ends
Convener			
Ms E Condie	National Centre	01.09.03	31.07.12
Internal Members			
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
Ms L Steckley	Social Work	01.09.09	31.07.12
Dr J Johnston	SIPBS	01.03.08	31.07.13
Dr S Kelly	Psychology	01.08.06	31.07.12
Dr N NicDaeid	Forensic Science	01.09.03	31.07.12
Dr P Riches	Bioengineering	01.08.07	31.07.13
Dr James Windmill	Electrical & Electronic Engineering	01.06.10	31.05.13
External Members			
Dr J Bunney	Chief Pharmacist (Retired)	01.11.04	31.07.13
Dr H Gray	Student Health Service Consultant, GRI (retired)	01.10.00	31.07.13
Lay Members			
Mr D Blyth	Lay	01.11.06	31.07.13
Mr C W Turner	Lay	01.10.04	31.07.13
Mrs M Whitehead	Lay	01.04.07	31.07.13

ANNEX 2

Risk Nbr	Description of risk	Significant consequences	Key controls and mitigating factors	Early warning mechanisms	Likelihood (L/M/H)	Impact (L/M/H)	Owner
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 and the Code of Practice 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.	**M**	**H**	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.	**L**	**H**	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 RKES for all projects; Management approval considered for all projects by Director of RKES and Deputy Principal; Regular monitoring of projects and DECs.	Negative feedback; Responses to monitoring.	**L**	**H**	UEC

| 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 RKES 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 RKES 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
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 RKES 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 RKES, and staff can identify grant proposals that require ethical approval; Increased liaison with DECs to raise awareness.	UEC convener reviews ethical status of all external projects; Negative feedback about research projects; RKES 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
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.	**L**	**M**	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 | **L** | **M** | 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. | **L** | **M** | UEC |

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 DECs; 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 UEC 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

Research students based abroad do not ensure University ethical approval is in place.	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.	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 with information regarding foreign travel; Regular reviews of suitability of all aspects of procedures; Any projects that require external funding are routed through RKES 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; Code of Practice is sent to local supervisor to ensure adherence to University procedures.	Negative feedback about research projects; Projects being submitted for external funding through RKES can be identified; UEC members drawn from across the research community within the University; Incomplete applications; Monitoring of projects and DECs.	**L**	**H**	UEC