UNIVERSITY OF STRATHCLYDE

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR ACADEMIC YEAR 2015/16

INTRODUCTION

The University Ethics Committee (UEC), together with its associated Departmental Ethics Committees (DECs) and School Ethics Committees (SECs) in the HASS Faculty, was established to consider general ethical issues relating to the University's teaching and research when such activity involves 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 UEC for 2015/16. Information on policy developments, approval of applications, monitoring of projects, training, and risk management is provided in the report. Research and Knowledge Exchange Services (RKES) took over the UEC Secretariat role for the UEC from Corporate Services in February 2010. During the period covered by this report, Helen Baigrie, RKES Contracts Manager, undertook the UEC Secretariat role, with administrative assistance from Angelique Laverty and Minute takers Andrew MacLellan and Christine Gallacher, all from RKES.

Aileen Stevenson in the Finance Office undertook confirmations of insurance cover for the studies seen by UEC and by Departmental and School Ethics Committees.

The Convener of the UEC is Dr Steve Kelly, School of Psychological Sciences and Health, who has been in this role since 1 August 2012. Dr Kelly has agreed to undertake a second term of office from 2015 to 2018.

Currently, (October 2016) Vice-Conveners are:

- Dr Helen Marwick   School of Education
- Ms Karyn Ross   Biomedical Engineering
- Dr Laura Steckley   School of Social Work & Social Policy

This report will be considered by Research & Knowledge Exchange Committee at its meeting on 22 November 2016.

1. Progress against targets

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 monitored.

2. Code of Practice

The 'Code of Practice on Investigations Involving Human Beings' was significantly revised in 2009. In 2011 a sub-group of the UEC was formed to undertake a further revision to the Code of Practice to incorporate changes to legislation, University processes and other relevant issues. The current Code of Practice, the seventh version, was finalised in September 2013. Subsequently, a re-launch event was held in March 2014. Departmental and School conveners and members were invited and many attended.

It is intended that, rather than have a major review of the Code of Practice every few years, revisions will be made on a continuing basis. For that reason, it was decided not to do a print run of the Code, but rather to make it available only online, via the Ethics website. Clearly, it will be necessary to number each iteration of the Code and to alert staff when substantive revisions have occurred.

3. Website

The Ethics website continues to be regularly updated by the UEC Secretariat with useful advice, submission deadlines and key documents. The Ethics website is the principal source of information for applicants and is promoted as the key source of information on ethics to staff and students. The website also has a presence on the R&KE Portal.

The current application form and guidelines on how to complete the form feature on the website.

4. Training

The following training activities were undertaken:

The Association for Research Ethics Annual Conference and AGM took place in November 2015 in London. The University of Strathclyde is a member. UEC Convener, Dr Steve Kelly, attended.

Training supplied by UEC:

Two half-day training sessions were run by UEC, in November 2015 and in February 2016, under the Researcher Development Programme, for all researchers. Other attendees were new UEC members, members of Departmental/School Ethics Committees and some Professional Services staff with an interest in or some responsibility for ethics matters. The sessions were presented by Dr Steve Kelly, UEC Convener and by Dr Helen Marwick, Vice-Convener. The training sessions included a valuable contribution on Data Management from Mr Andrew MacLellan, Research Data Support Officer in RKES, who is one of the Minute takers for UEC.

The Department of Biomedical Engineering requested a presentation on ethics as part of its Clinical Awareness Training Day in July 2016. The ethics training session was presented by Mrs Shirley Andrews, a Lay Member of UEC.

Further training events are planned for 2016/17.

Conveners of Departmental Ethical Committees (DECs) and School Ethics Committee (SECs) have an open invitation to attend UEC as observers. Some have taken up this opportunity.

5. Strathclyde's Membership of AfRE (Association for Research Ethics)

The University has continued its membership subscription to AfRE. The UEC Secretariat has arranged electronic access to AfRE documents, including the Research Ethics Review Journal, for all UEC members. As AfRE is currently under re-organisation, it is likely that there will not be a conference in 2016.

6. Review and Approval of Applications

UEC meets once per month, on the first Thursday of the month. The papers for each meeting, and a Sharepoint link, are distributed to members so that the members receive the papers/link at least a week before the meeting.

At the meeting, one member leads on an application and then UEC discusses the application and agrees on a response to be sent by email to the applicant, once the Minutes for that meeting have been approved by the Convener.

The options open to UEC in its response to applicants, following review, are:

•   Approval
•   Rejection
•   Re-submission
•   Approval by Convener's Action subject to revisions to be made by the applicant.

In all but one cases the feedback from UEC to applicants was the last of those options - i.e. approval by Convener's Action with requests for further information and revisions to the application form or supporting documentation – no applications were approved at first review and none were rejected. UEC asked one applicant to re-submit an application, as the application contained too many fundamental errors for it to be approved by Convener's Action.

33 applications were reviewed by UEC in 2015/16. The majority of these were approved by UEC following the undertaking of revisions by the applicants. A very small number have been delayed due to issues with the applicants.

On average, applicants received feedback on their initial application within ten working days of the UEC meeting at which they were reviewed.

On average, excluding outliers (applicants who took several months to respond to the UEC feedback), applications were approved within 23 working days of the UEC meeting. Please note that this figure includes the time taken for applicants to resubmit their amended documentation, or the subsequent requests from the Convener for further clarification in response to amendments (at least half of the resubmissions required further work). The majority of final amendments, once received, were approved by Convener's Action within two working days.

These turnaround times are well within the guidelines stated on page 23 of the Code of Practice, "From the time of receipt of an application, it would normally be hoped that the Committee will make its decision within 60 days. However, if the Committee seeks further information from the investigators then the timescale is suspended until the Committee is satisfied that all its points of concern have been answered."

14 NHS applications were submitted to or logged with the Ethics Team and 12 endorsed by the Convener on behalf of UEC during 2015/16, following favourable opinion from NHS itself.

Three applications that had been approved by external organisations were endorsed by the Convener on behalf of UEC.

The Manager of UEC Secretariat in RKES approved sponsorship for nine externally-funded applications that had obtained ethical approval through their DEC/SEC.

Two submissions were received from external organisations that have no ethical review process – one was given a favourable opinion and the other was reviewed but subsequently withdrawn.

The fee for review of ethical applications from external organisations had been set at £450. One of the two external submissions was charged £450 and the other, a Strathclyde spin-out, was charged £300, based on advice from the Director of RKES. The lower fee was determined probably based on the applicant's level of association with the university. However, UEC recommends that RKES develop a formal pricing structure taking these levels into account.

The other external submission was from an organisation that undertakes research into drug misuse. To avoid the possibility of contravening CRUK's rules on universities' working with tobacco companies, UEC has decided to adopt a conservative approach and will not provide ethical review for research funded by tobacco companies.

7. Monitoring of Projects

The UEC monitors the progress of each of the applications which is approved by it, both annually and at the end of each protocol.

8. Departmental/School Ethics Committees (DECs/SECs)

The UEC also monitors the activities of all the DECs and SECs on an annual basis. The DECs/SECs 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 DECs/SECs may have.

As UEC has identified some weaknesses in some DECs/SECs, it is proposed that new DEC/SEC members should be required to attend at least one UEC meeting - all DEC/SEC members, new or otherwise, have received an open invitation to attend, and some already have.

In addition, UEC plans to arrange a training session specifically for DEC/SEC members. *If RKEC endorses it*, new DEC/SEC members will be required to attend the training session and to attend at least one UEC meeting.
Those options will also be open to existing DEC/SEC members.

9.   CHANGES TO BE EFFECTED: HaSS Procedures

At time of writing (October 2016) it had just been agreed that there will be a change to the processing of ethical applications from the Faculty of Humanities and Social Sciences (HaSS). Until now, the Research & Knowledge Exchange Team (RaKET) in HaSS has processed aspects of ethical applications destined for UEC. It was agreed that there was a degree of duplication of work between HaSS and the UEC Ethics Team, and that the HaSS applicants had the disadvantage of having to work to an earlier deadline than the other faculties. From now, HaSS applicants to UEC will follow the same procedures as the other faculties.

10. UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

UEC continues to have a wide range of expertise and knowledge across its membership.

Dr Steve Kelly (Psychology) has been Convener of UEC since August 2012.

There are currently (October 16) three Vice-Convenors supporting the work of the UEC

Dr Laura Steckley (School of Applied Social Science)
Dr Helen Marwick (Education)
Ms Karyn Ross (Biomedical Engineering
There is currently one vacancy for an internal member.

The current membership of the UEC is included as Annex 1.

The Code of Practice states that 'Members of the UEC will normally be appointed for three years at a time, and may be reappointed for subsequent years.' UEC proposes that, to avoid the simultaneous departure of several members who joined at around the same time, and the resulting loss of expertise that would follow, members should not be restricted to three-year appointments, but should resign from UEC when they wish, subsequent to the initial three-year appointment. The staggered departures would help to retain expertise in particular areas, with experience suggesting that the majority of members are willing to serve a second three-year term or more.

11. RISK MANAGEMENT

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 UEC Secretariat in RKES, which confirms if the University will sponsor each project.

Aileen Stevenson of Finance created an insurance questionnaire that now forms part of the application form. Only research studies that feature certain criteria require to be reviewed for insurance confirmation by Finance. DECs and SECs are also required to review the insurance questionnaire and report to Finance on relevant studies. Examples of the criteria requiring referral to Finance Office are: work

overseas, work involving children under 5, pharmaceutical product design and research involving aircraft or aerial devices.
Use of this questionnaire has streamlined the process.

Finance Office then liaises with the University's insurers to establish whether sufficient cover is in place for applications which feature the criteria.
Researchers must not commence their work until all aspects of this process are confirmed. This is confirmed in email contact with researchers.

The UEC Secretariat consulted Safety Services on which, if any, changes to references to Health and Safety and Risk Management were required in the Code of Practice. Safety Services provided useful advice in relation to current recommendations on risk assessment as well as Health & Safety. The Code of Practice and Application Form have been updated to include, amongst other points, advice for applicants that the University's Risk Management Framework document should be consulted and use of the risk-rating tool within it applied.

This has led to many questions from applicants on the requirement to complete an 'S20' from for every research study. Whilst responsibility for ensuring that staff complete the S20 forms lies with Heads of Departments/Schools, it has become apparent to UEC that awareness of the S20 requirement is patchy across the University, even amongst Heads of Departments/Schools. Safety Services has been informed and now looks at the S20 forms that accompany ethics applications, with a view to monitoring the quality of the risk assessments.

12. BUDGET

At time of writing (October 2016) the budget for fiscal year 2016/17 has not yet been notified.

The usual uses of the budget are:

Association for Research Ethics (AfRE) membership
Travel and attendance by Convener and members of UEC at Ethics training events
Travel of Lay and External members to attend UEC meetings
Administration costs – printing, copying, stationery
Catering (tea/coffee) for UEC meetings and training events
One annual lunch for members

13. NEXT STEPS

A copy of this report will be provided to the Research and Knowledge Exchange Committee for approval at its 22 November 2016 meeting.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP October 2016

Name	**School/Department/Category**	**Date Appointed**
Convener		
Dr Steve Kelly	School of Psychological Sciences & Health	01.08.06
Internal Members		
Dr Calvin Burns	HRM	01.08.08
Professor Luke Chamberlain	SIPBS	01.08.12
Dr Sylvie Coupaud	Biomedical Engineering	01.03.15
Dr Penny Haddrill	P & A Chemistry	01.11.15
Dr Helen Marwick (VC)	Education	01.01.12
Professor Kenneth Norrie	Law School	01.01.15
Dr Susan Rasmussen	School of Psychological Sciences & Health	01.08.12
Ms Karyn Ross (VC)	Biomedical Engineering	01.08.12
Dr Laura Steckley (VC)	School of Applied Social Science	01.09.09
Dr James Windmill	Electrical & Electronic Engineering	01.06.10

One Vacancy

External Members

Ms Shirley Andrews (Retired)	Head of Training, Police Scotland	01.05.14
Dr Gordon Hamilton	Occupational Health Physician/ Honorary Senior Lecturer (GU)	06.09.12
Mr James Wallace	Pharmacist (Retired)	01.08.13

Lay Members

Mr Nicholas Shearer	(IT Consultant)	01.03.14
Dr Barbara West	(Retired GP)	02.08.12
Vacancy		