# UNIVERSITY OF STRATHCLYDE UNIVERSITY ETHICS COMMITTEE

#### **ANNUAL REPORT FOR CALENDAR YEAR 2014/15**

#### **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 2014/15. 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, Angelique Laverty and Andrew MacLellan of RKES undertook the UEC Secretariat role.

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 undertaken this role since 1 August 2012. He has indicated willingness to undertake a second term of office from 2015 to 2018.

Currently, (August 2015) 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 8 September 2015.

### 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 sixth 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 large 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 to the fact that changes 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 on 14th November 2014 in London. Strathclyde is a member. UEC Convener Dr Steve Kelly attended.

Training supplied: Two half-day training sessions were run by UEC, in November 2014 and in February 2015, under the Research Development Programme, for all researchers. They were undertaken by Dr Steve Kelly, UEC Convener. An additional training event for the Business School was run by Dr Calvin Burns, UEC member from SBS.

Further training events are planned for 2015/16. Conveners of Departmental Ethical Committees (DECs) and School Ethics Committee (SECs) were been invited to attend UEC as observers. Some have taken up this opportunity.

#### 5. Association for 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.

#### 6. Approval of Applications

49 applications were reviewed by UEC in 2014/15. The majority of these have been approved by UEC following the undertaking of revisions by the applicants. A very small number have been delayed due to issues with the applicants.

Additionally, nine NHS applications were endorsed by the Convener on behalf of UEC during 2014, following approval from NHS itself.

Also, two 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 five externallyfunded applications that had obtained ethical approval through their DEC/SEC

On average, applicants received feedback on their initial application within six working days of the UEC meeting at which they were reviewed. In all cases the feedback included requests for further information and amendments to the application form or supporting documentation – no applications were approved at first review.

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."

## 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. Monitoring of Departmental/School Ethics Committees

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.

#### 9. CHALLENGES AND ISSUES

Some researchers have reported difficulty in obtaining appropriate Protection for Vulnerable Groups (PVG) clearance from Disclosure Scotland. Lorna Dougall is the university's PVG liaison and noted that Disclosure Scotland were not considering research posts to be regulated work and therefore not requiring PVG though further discussion on this matter was planned. In order to ensure that the Code of Practice offers the most accurate advice on PVG, a working party consisting of Steve Kelly as Convener, Laura Steckley, Vice-Convener and involved in child protection issues at CELCIS and Shirley Andrews, bringing expertise from Police Scotland has been formed. The remit of the working party is to liaise with Lorna Dougall, HR and Disclosure Scotland in order to formulate the most appropriate amendment for the Code of Practice. An agreed paragraph has been formulated for insertion into the Code of Practice and further developments from Disclosure Scotland will be monitored.

#### 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.

Three Vice-Convenors have left the University or resigned from UEC due to competing workload issues over the last year (Professor Niamh Nic Daeid (P & A Chemistry), Dr Phil Riches (Biomedical Engineering), and Mr Douglas Blyth, a solicitor and a Lay Member.

There are currently (August 15) three Vice-Convenors supporting the work of the UEC: Dr Laura Steckley (School of Applied Social Science), Dr Helen Marwick (Education) and Dr Karyn Ross (NCPO).

Dr Sylvie Coupaud (Biomedical Engineering) joined the Committee in March 15.

Emeritus Professor John Blackie (Law School) left UEC at the end of 2014 and was replaced by Professor Kenneth Norrie of the Law School.

Alexander Cameron CBE, a former Director of Social Work, has expressed an interest in becoming an External Member, initially from the beginning of 2015, but has had his current remit as chair of a government enquiry extended and so remains as a potential future member on the committee.

There is currently one vacancy for an internal member.

The current (August 15) membership of the UEC is included as Annex 1.

#### 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 also 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 applied 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, information 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 staff to 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 has agreed to look at the S20 forms that accompany ethics applications, with a view to Safety Services monitoring the quality.

A continuing concern for UEC is the quality of student applications. Supervisors are the Chief Investigators on behalf of their students, and are responsible for the content of the application. However, it is clear from some applications that some Supervisors are not overseeing the students' ethics submissions.

Professor Tim Bedford sent an email to Heads of Departments & Schools asking the Heads to remind staff of their responsibilities in this area.

#### 12. BUDGET

The UEC was allocated a running costs budget of £3,000 for 2014/15. In addition, UEC reviewed an ethical application for an external organisation, at a charge of £450 – those funds were paid into the UEC budget. The balance at financial year end 31 July 2105 was £101.37.

At time of writing (August 2015) the budget for fiscal year 2015/16 has not yet been notified.

The principal uses of the budget are:

Cost of Association for Research Ethics (AfRE) membership Cost of 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 Savings have been made by opting to headhunt potential Lay/External members with appropriate expertise, rather than by paying for advertising in the local press, which cost £2000 during the last recruitment round. It is anticipated that this method of recruitment will be used where possible in future given its current success.

## 13. NEXT STEPS

A copy of this report will be provided to the Research and Knowledge Exchange Committee for approval at its 16 September 2015 meeting.

## **ANNEX 1**

# **UNIVERSITY ETHICS COMMITTEE**

# **MEMBERSHIP August 2015**

| Name                                   | Category/Faculty  | Date Mem appointed | bership<br>ends |
|--|---|--------------------|-----------------|
| <b>Convener</b><br>Dr S Kelly          | School of Psychological Sciences<br>& Health                    | 01.08.06           | 31.07.18        |
| Internal Members<br>Professor K Norrie | Law School  | 01.01.15           | 31.12.2017      |
| Dr Sylvie Coupaud                      | Biomedical Engineering  | 01.03.15           | 28.02.18        |
| Dr C Burns                             | HRM   | 01.08.08           | 31.07.17        |
| Dr L Steckley (VC)                     | School of Applied Social Science                                | 01.09.09           | 31.07.18        |
|  |   |                    |                 |
| Dr James Windmill                      | Electrical & Electronic Engineering                             | 01.06.10           | 31.05.16        |
| Dr Helen Marwick (V                    | C) Education  | 01.01.12           | 31.12.17        |
| Ms K Ross (VC)                         | Biomedical Engineering  | 02.08.12           | 31.07.18        |
| Dr S Rasmussen                         | School of Psychological Sciences<br>& Health                    | 02.08.12           | 31.07.18        |
| Dr L Chamberlain                       | SIPBS   | 02.08.12           | 31.07.18        |
| Vacancy                                |   |                    |                 |
| External Members                       |   |                    |                 |
| Mr J Wallace                           | Pharmacist (Retired)  | 01.08.13           | 31.07.16        |
| Dr G Hamilton                          | Occupational Health Physician/<br>Honorary Senior Lecturer (GU) | 06.09.12           | 31.07.18        |
| Ms Shirley Andrews (Retired)           | Head of Training, Police Scotland                               | 01.05.14           | 30.04.17        |

# **Lay Members**

| Dr B West    | Lay (Retired GP)    | 02.08.12 | 31.07.18 |
|--------------|---------------------|----------|----------|
| Mr N Shearer | Lay (IT Consultant) | 01.03.14 | 28.02.17 |