

UNIVERSITY OF STRATHCLYDE
UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR CALENDAR YEAR 2012

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 2012. 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 and Murray Dickson covered the UEC Secretariat role.

The UEC was supported with respect to insurance by Tim Faenrich in the Finance Office.

The Convener of the UEC is Dr Steve Kelly, who took over the role on 1 August 2012, following the departure of Elizabeth Condie as Convener at the end of July 2012.

This report will be considered by Research & Knowledge Exchange Committee at its meeting on 3 September 2013.

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 another revision to the Code of Practice to incorporate changes to legislation, University processes and other relevant issues. It is envisaged that this will be finalised in September 2013.

3. Website

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

4. Training

The following training activities were undertaken:

The UEC Convener, Dr Steve Kelly, attended a workshop in Cardiff run by the Association of Research Ethics Committees AREC.

A lay member attended an NHS-run workshop 'Informed Consent: Legal & Ethical Issues in Consent (Adult)'

Helen Baigrie and Murray Dickson of the RKES Secretariat attended an NHS-run workshop 'Clinical Trial of an Investigational Medicinal Product' (CTIMP).

Training supplied:

In 2012, three half-day sessions were run by UEC members – one for the HaSS Faculty Transferable Skills Programme and another two, under the Research Development Programme, for all researchers. Following these, enquiries were made as to the possibility of allowing these sessions to be credit bearing with respect to postgraduate awards.

In addition, a UEC member in the Business School gave a talk on ethics to business and management PhD students from all of Scotland, as part of the SBS ESRC Doctoral Training Centre remit.

5. Association for Research Ethics Committees (AREC)

The University has continued its membership subscription to AREC. The UEC Secretariat has arranged electronic access to AREC documents, including the Research Ethics Review Journal, for all UEC members.

8. Approval of Applications

42 applications were submitted for UEC approval in 2012. Four were withdrawn and 38 approved. Of the four withdrawn, two were referred to the relevant DEC/SEC. Additionally, eight NHS applications were approved by the Convener on behalf of UEC during 2012, following approval from NHS itself. Two applications originally submitted to NHS were withdrawn.

The UEC Secretariat in RKES also approved sponsorship for 12 externally-funded applications that had obtained approval from 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 (three 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 does not exclude 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 were approved by Convener's Action within two working days.

These turnaround times are well within the guidelines stated on page 20 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."

9. 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. Monitoring for 2012 will take place in August/September 13.

10. 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.

The annual monitoring forms for 2012 have been issued and received. Any comments from DECs/SECs will be noted and acted upon where appropriate. Any outstanding reports will be followed up.

11. CHALLENGES AND ISSUES

Before the re-structuring of the jobs framework, Chief Investigators (CIs) had to be Ordinance 16 staff. Student applications are becoming more numerous, particularly in HASS. As Supervisors are required to be the CI on students' ethics applications, it was necessary for the UEC to investigate what the equivalent of Ordinance 16 is now, and what is acceptable to the insurers regarding risk. This was investigated, in consultation with HR and the insurance brokers, and it was agreed that CIs must be minimum Grade 7 (or equivalent) as this job description entails supervision.

It was understood that in SBS, many supervisors are non-University staff and UEC was informed that those supervisors are given Honorary or Visiting Researcher contracts.

This change will be incorporated into the revised Code of Practice, Application Form and Guidance Notes for the Application Form.

12. UNIVERSITY ETHICS COMMITTEE MEMBERSHIP

Dr Steve Kelly has been Convener of UEC since August 2012. There are currently four Vice-Convenors supporting the work of the UEC: Professor Niamh Nic Daeid, Dr Phil Riches, Ms Laura Steckley and Mr Douglas Blyth. Mr Blyth is a solicitor and a Lay Member.

The current (August 13) membership of the UEC is included as Annex 1.

13. 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, who also confirms 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's insurers to establish whether sufficient cover is in place for each application. 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 will be 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.

14. BUDGET

The UEC has a running costs account with the budget currently (in August 2013) standing at £4,030. The budget is used by members to attend appropriate training events and for catering at meetings

15. NEXT STEPS

A copy of this report will be provided to the Research and Knowledge Exchange Committee for approval at its 3 September 2013 meeting.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP 2013

Name	Category/Faculty	Date appointed	Membership ends
Convener			
Dr S Kelly	School of Psychological Sciences & Health	01.08.06	31.07.15
Internal Members			
Professor J Blackie	Law School (Emeritus)	01.05.05	31.07.14
Dr C Burns	HRM	01.08.08	31.07.14
Ms L Steckley (VC)	School of Applied Social Science	01.09.09	31.07.15
Professor N NicDaeid (VC)	Forensic Science	01.09.03	31.07.15
Dr P Riches (VC)	Biomedical Engineering	01.08.07	31.07.16
Dr James Windmill	Electrical & Electronic Engineering	01.06.10	31.05.16
Dr Helen Marwick	Education	01.01.12	31.12.14
Ms K Ross	Biomedical Engineering	02.08.12	31.07.15
Dr S Rasmussen	School of Psychological Sciences & Health	02.08.12	31.07.15
Dr L Chamberlain	SIPBS	02.08.12	31.07.15
Vacancy			
External Members			
Mr J Wallace	Pharmacist (Retired)	01.08.13	31.07.16
Dr G Hamilton	GP (Retired)	06.09.12	31.07.15
Vacancy			
Lay Members			
Mr D Blyth (VC)	Lay	01.11.06	31.07.16
Dr B West	Lay	02.08.12	31.07.15
Vacancy			