UNIVERSITY OF STRATHCLYDE

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR ACADEMIC YEAR 2018-19

INTRODUCTION

The University Ethics Committee (UEC) is the body responsible for giving ethical approval for investigations. UEC and associated Departmental and School Ethics Committees (DECs & SECs) consider ethical issues relating to University activity involving investigations in which people are participants. UEC provides impartial advice in order to protect the dignity, rights, safety and well-being of all participants and investigators. Ethical approval, 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 2018-19. Information on policy developments, approval of applications, monitoring of projects, training, and risk management is provided in the report. Research & Knowledge Exchange Services (RKES) is responsible for providing the UEC Secretariat. During academic year 2018-19 Angelique Laverty, RKES Administrator, undertook the UEC Secretariat role and minutes were taken by Andrew MacLellan. Judith Billcliffe 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 UEC (since September 2018) is Philip Winn, Emeritus Professor in SIPBS. Currently, (July 2018) Vice-Conveners are:

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

This report will be considered by the Research & Knowledge Exchange Committee at its meeting on 03 September 2019.

1. Progress against targets

UEC does not have specific targets. Activities essential to the effective and efficient operation of the UEC are monitored including for example training uptake and the progress of approved projects.

2. Code of Practice

The *Code of Practice on Investigations Involving Human Beings* is available online, accessed through the Ethics website (https://www.strath.ac.uk/ethics/). The current edition is the eighth. The General Data Protection Regulation (GDPR) now in force made it necessary to refresh Participant information Sheets, Privacy Notices and guidance notes for applicants.

3. Website

The Ethics website – updated regularly – is the principal source of information for applicants and is promoted as the key source of information on ethics to staff and students. It has a presence on the R&KE Portal. Application forms and guidelines are on the website.

4. Training

Half-day training sessions were run by UEC on 07 November 2017 and on 21 January 2019, under the Researcher Development Programme. The sessions were presented by Professor Philip Winn and included information on Data Management from Ms Marie Henderson Research Data Support Officer in RKES (November) and Professor Winn (January).

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.

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.

All members familiarize themselves with all the applications but at the meeting, one member leads on an application with other members adding further contributions. After discussion a response is agreed, to be sent by email to the applicant after the Minutes for the meeting have been approved by the Convener.

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

- Approval as it stands
- Outright Rejection
- Request for re-submission to UEC for re-review
- Approval by Convener's Action subject to minor revisions.

The table below shows the numbers of applications in each category. In most cases the outcome of the discussion at UEC was approval by Convener's Action with

requests for further information and revisions to the application form or supporting documentation.

Initial Decision by UEC	Number	Pending	Approved
Approval	2		
Rejection	5		3 *
Resubmit to UEC	12	3	9
Convener's action	49	4	45
Total applications	68		

* Rejection of applications never happens after first submission. Comments are provided to applicants and re-review undertaken but never more than three times. After this the application is rejected with a full rationale provided. Applicants are at liberty to give fundamental reconsideration to their projects and bring back fresh proposals. Three of the rejected applications were substantively reworked and submitted as (in effect) fresh applications – these are the three in the approved column. Two of the rejected applications have not as yet resurfaced.

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 25 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.*

29 NHS applications were submitted to or logged with the Ethics Team and 13 endorsed by the Convener on behalf of UEC during 2018-19, following favourable opinion from the NHS itself.

Two applications that had been approved by external organisations other than NHS were endorsed by the Convener on behalf of UEC.

The Manager of UEC Secretariat in RKES approved sponsorship for 28 externally-funded applications that had obtained ethical approval through their DECs/SECs.

7. Monitoring of Projects

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

2018/19. Applicants are required to detail anything unexpected and confirm that they are adhering to protocols

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

The UEC monitors the activities of all the DECs and SECs annually. 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. Monitoring is currently underway for 2018/19

9. University Ethics Committee Membership

Professor Philip Winn (SIPBS) is convener (since September 2018) and there are four Vice-Convenors: Dr Helen Marwick (Education), Ms Karyn Ross (Biomedical Engineering), Dr Laura Steckley (School of Applied Social Science) and Dr Barbara West, Lay Member. The full 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 proposed in in 2017 that, to avoid the simultaneous departure of several members who had 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.

10. Risk Management

Risk assessment is an integral to the work of UEC with members evaluating potential risks to human participants and the potential benefit of the research. 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 (Finance Office) created an insurance questionnaire that forms part of the application form. Only research studies that feature certain criteria require review 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.

The University's 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 form (now eRisk assessment) for every research study. Whilst responsibility for

ensuring that staff complete the eRisk assessment lies with Heads of Departments/Schools, it has become apparent to UEC that awareness of the eRisk requirement is patchy across the University, even amongst Heads of Departments/Schools. Safety Services has been informed and now looks at the eRisk assessments that accompany ethics applications, with a view to monitoring the quality of the risk assessments. Safety Services has acknowledged that this has helped raise awareness of the need for a risk assessment to be undertaken for every research study.

11. Budget

At time of writing (August 2019) the budget for fiscal year 2019/20 has not yet been notified. Budget is necessary for:

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

12. Next Steps

A copy of this report will be provided to the Research and Knowledge Exchange Committee for approval at its 03 September 2019 meeting.

The Convener of UEC, Professor Philip Winn, has been in post since September 2018. On taking up the post – succeeding Dr Steve Kelly – it was apparent that there was no immediate cause for concern and that committee members discharged their duties with considerable care and thoughtfulness. Examination of each application is thorough and forensic.

Nevertheless, having been in post for a year, this is an opportune moment for review. What is in train is a series of meetings between the Convener and DEC/SEC Conveners/ Members to look into how well procedures are operating across the University; to find examples of good practice and disseminate them; to identify any local or general problems and find solutions; and to review the forms and published materials.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP AUGUST 2019

<u>Name</u>	<u>School/Department/Category</u>	<u>Date</u> <u>Appointed</u>
Convener		
Prof Philip Winn	SIPBS	01.08.18
Internal Members		
Dr Joanne Cleland	Speech & Language Therapy	01.03.18
Dr Sylvie Coupaud	Biomedical Engineering	01.03.15
Dr Penny Haddrill	P & A Chemistry	01.11.15
Dr Genevieve Lennon (on mat leave)	Law	01.03.17
Dr Helen Marwick (VC)	Education	01.01.12
Dr Patrick McColgan	Accounting & Finance	01.08.18
Professor Kenneth Norrie	Law School	01.01.15
Dr Chris Prior	SIPBS	01.09.17
Dr Susan Rasmussen	Psychological Sciences & Health	01.08.12
Ms Karyn Ross (VC)	Biomedical Engineering	01.08.12
Dr Laura Steckley (VC)	Applied Social Science	01.09.09
Prof James Windmill	Electrical & Electronic Engineering	01.06.10
External Members		
Ms Shirley Andrews	Head of Training, Police Scotland (Retired)	01.05.14
Mr James Wallace	Pharmacist (Retired)	01.08.13
Dr Barbara West (VC)	Retired GP	02.08.12
Lay Members		
Mr Nicholas Shearer	(IT Consultant)	01.03.14
Vacancy		