

RKEC 23-24/Sept Paper X

PAPERS TO BE CONSIDERED BY THE UNIVERSITY RESEARCH AND KNOWLEDGE EXCHANGE COMMITTEE (RKEC)

| University Ethics Committee Convener's Annual Report | | | |
|--|---|--|--|
| Date of Meeting: | 19 September 2023 | | |
| Purpose: | Report of Activity August 2022 to July 2023 and indication of plans for 2023-24 | | |
| Intended Outcome: | For RKEC's general approval | | |
| Key points: | Review and approval of applications Risk Management Next Steps | | |
| Paper Submitted by: | University Ethics Committee | | |
| Resource Implications: | No | | |
| Equality, Diversity & Inclusion: | An EIA has not been undertaken, however, a key purpose of the University Ethics Committee is to provide impartial advice to participants and investigators and to protect the dignity, rights, safety and well-being of all actual and potential research participants | | |
| University Archives: | Open | | |
| Key Contact(s): | Professor Philip Winn, SIPBS, <u>philip.winn@strath.ac.uk</u> Ms Angelique Laverty, RKES, <u>a.laverty@strath.ac.uk</u> | | |
| Date of Production: | 05 September 2023 | | |

THE QUEEN'S ANNIVERSARY PRIZES 2019 & 2021 For Higher and Further Education UNIVERSITY OF THE YEAR 2012 & 2019 Times Higher Education SCOTTISH UNIVERSITY OF THE YEAR 2020 The Times & The Sunday Times

UNIVERSITY OF STRATHCLYDE

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR ACADEMIC YEAR 2022-23

INTRODUCTION

The University Ethics Committee (UEC) is the body responsible for giving ethics approval for investigations. UEC and associated Departmental Ethics Committees (DECs) 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 2022-23. 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 2022-23, Angelique Laverty, Research Ethics & Governance Manager, undertook the UEC Secretariat role. Lynsey Hamilton, Financial Accountant (Accountancy Services, Finance), undertook confirmations of insurance cover for the studies reviewed by UEC and by Departmental Ethics Committees.

The Convener of UEC (since September 2018) is Philip Winn, Emeritus Professor in SIPBS. Currently, (September 2023) Vice-Conveners are:

- Dr Joanne Cleland, Psychological Sciences and Health
- Dr Patrick McColgan, Accounting and Finance
- Ms Karyn Ross, Biomedical Engineering
- Dr Barbara West, Lay Member

This report will be considered by the Research & Knowledge Exchange Committee at its meeting on 19 September 2023.

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 (<u>https://www.strath.ac.uk/ethics/</u>). The current edition is the eighth.

Rather than further modify the existing CoP, the Convener decided that a more substantial revision is required and work on this is underway.

The intention is to provide simpler documentation than the current CoP and to divide this into three sections:

- (1) The broad principles of ethics review
- (2) Guide to completing an application for ethics approval
- (3) An expanded glossary including links to further information

This will involve liaising with colleagues including Legal, Information Governance and Health & Safety and will be sent to AP/DAP action group for comment before presentation to RKEC.

3. Website

The University Ethics Committee 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 RKES Portal. Application forms and guidelines are on the website.

This year much progress has been made on the development of an online ethics application system. Preparation work for the online forms is complete. Development work is done by Information Services Directorate and has been impacted by resource issues within ISD. These issues have meant that ISD are no longer able to develop the wider system at this time, but have been working on a stand-alone ethics application form which will replicate the previous form, but will include several improvements:

- (1) Smartform: allows application form to be filtered so applicants only complete relevant sections quicker and easier for applicants.
- (2) Mandatory fields quicker and easier for applicants and for UEC administration.
- (3) Improved guidance and link to web pages to support researchers through the ethics processes, including external approvals. Pointing researchers to all relevant guidance and requirements will strengthen and align Strathclyde's ethics review systems thus mitigating the risk of breaches of ethics protocols and non-compliance with funder/legislative requirements.

- (4) Auto-generation of emails to Finance, IGU, SHaW, RDMS where appropriate.
- (5) Auto-alert UEC administration for DEC reviewed studies with external funding (for sponsorship review).
- (6) Aligned with the increased sectoral focus on research governance which necessitates a more comprehensive approach to ethics management which facilitates monitoring of the Departmental Ethics Committees' procedures and compliance checks of approved protocols.
- (7) Post-approval: autogenerate monitoring email one year after approval. More is needed on monitoring, but this is a first step.
- (8) A further benefit of the stand-alone form is that it will necessitate the development of new training for applicants. Such training will incorporate aspects of existing research integrity training. Breaches in research ethics, data security and research integrity represent a risk to the University, therefore, there is significant justification for requiring mandatory training on these topics for staff in relevant roles. This could include mandatory refresher training and aligns with our need to increase monitoring.

New guidance is being prepared to complement the updated CoP and online guidance; this will be available on the UEC website.

4. Training

- (1) The Convener delivered the 'Researchers' Guide to Ethics' training course to PGRs throughout the year. This course is part of the Researcher Development Programme.
- (2) UEC members delivered ethics training to Research Interns@Strathclyde students.
- (3) Ethics Manager delivered training and workshops as part of Research Integrity Week.
- (4) Convener and Ethics Manager are in discussions with OSDU on developing Spiral programmes on ethics training for staff including specific training for supervisors. The intention is for completion of these courses to become mandatory for applicants for ethics approval.
- (5) Revised training is planned for Departmental Ethics Committees which will include live and online sessions.

5. Review and Approval of Applications

During 2022-23 UEC met in-person each month.

In all cases, the papers for each meeting, and a Share Point link, are distributed to members. For normal meetings, members receive the papers/link at least a week before the meeting.

For all reviews, normal or fast-track, one member led on the application with other members adding further contributions. After discussion a response is agreed, to be sent by email to applicants 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:

- (1) Approval as it stands
- (2) Outright Rejection this would include advice for applicants on study re-design or information on where to seek further support if appropriate
- (3) Request for re-submission to UEC for re-review
- (4) 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 that an application may be approved by Convener's Action with requests for further information and revisions to the application form or supporting documentation.

One application was passed to the Senior Officer with responsibility for UEC, Professor Bedford, for sponsorship and management risk approval because the Ethics Manager considered it to be of medium/high risk and so out-with their delegated responsibility to approve. This study is still being assessed.

| New Applications | Number | Pending | Approved |
|-------------------------|--------|----------------|----------|
| Initial Decision by UEC | | | |
| | | | |
| Approval | 1 | | 1 |
| Rejection | 0 | | |
| Resubmit to UEC | 3 | 1 withdrawn | 1 |
| | | and 1 rejected | |
| Convener's Action | 43 | 4 | 39 |
| | | | |
| | | | |
| Total applications | 47 | | |
| | | | |

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

18 NHS applications were submitted to or logged with the Ethics Manager and 15 endorsed by the Convener on behalf of UEC during 2022-23, following favourable opinion from an NHS Research Ethics Committee.

The Ethics Manager approved sponsorship for 22 externally funded applications that had obtained ethics approval through DECs.

6. Monitoring of Projects

UEC monitors the progress of each of the investigations it has approved, both annually and at the end of each protocol. Monitoring is currently underway for 2022-23. Applicants are required to detail anything unexpected and confirm that they are adhering to protocols. This process will be enhanced by the introduction of online monitoring when the online system is in place.

7. Departmental Ethics Committees (DECs)

The UEC monitors the activities of the DECs annually. The DECs 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 2022-23.

There have been suggestions from the department that EEE would benefit from having its own DEC. This will be discussed in the coming academic year.

8. University Ethics Committee Membership

Professor Philip Winn (SIPBS) is Convener (since September 2018) and there are four Vice-Conveners: Dr Joanne Cleland (Speech & Language Therapy), Dr Patrick McColgan (Accounting & Finance), Ms Karyn Ross (Biomedical Engineering), 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 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, after the initial three-year appointment.

9. Risk Management

Risk assessment is 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 whether the University will sponsor each project. The insurance questionnaire and eRisk assessments are being used successfully.

10. Budget

At time of writing (September 2023) the budget for fiscal year 2023-24 has not been notified. Budget is necessary for:

- (1) Travel and attendance by Convener and members of UEC at Ethics training events
- (2) Travel of Lay and External members to attend UEC meetings
- (3) Administration costs printing, copying, stationery
- (4) Catering (tea/coffee) for UEC meetings and training events
- (5) One annual lunch for members

11. Next Steps

- (1) Undertaking major revisions to the Code of Practice.
- (2) Moving the ethics application and monitoring process online the design of the online system is complete; UEC awaits development by ISD.
- (3) Reviewing ethics policies and procedures to establish a comprehensive and aligned institutional research ethics framework including AWERB and the Genetic Modification Safety Committee.
- (4) Updating training and guidance for all staff, including refresher courses for more senior staff. OSDU will facilitate this training.
- (5) Providing HoDs with clear guidance on their responsibilities regarding approving sponsorship of DEC reviewed studies.
- (6) Increasing monitoring of the DECs with a light touch process.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP AUGUST 2023

| <u>Name</u> | Department/Category | Date Appointed |
|-------------------------------|---------------------------------------|----------------|
| Convener | | |
| Professor Philip Winn | SIPBS | 01.08.18 |
| Internal Members | | |
| Dr Joanne Cleland (VC) | Psychological Sciences & Health | 01.03.18 |
| Dr Penny Haddrill 01.11.15 | Pure & Applied Chemistry | |
| Dr Mark Heslop | Chemical & Process Engineering | 01.11.22 |
| Dr Mariya Ivancheva | Institute of Education | 01.11.22 |
| Dr Patrick McColgan (VC) | Accounting & Finance | 01.08.18 |
| Dr Robert Porter | Social Work & Social Policy | 01.02.23 |
| Dr Chris Prior | SIPBS | 01.09.17 |
| Ms Karyn Ross (VC) | Biomedical Engineering | 01.08.12 |
| Dr Rhonda Wheate | Law School | 10.08.23 |
| External Members | | |
| Ms Shirley Andrews | Retired Head of Training, Police Scot | and 01.05.14 |
| Mr Nicholas Shearer | IT Consultant | 01.03.14 |
| Dr Barbara West (VC) | Retired medical doctor | 02.08.12 |