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

University Ethics Committee Convener's Annual Report	
Date of meeting:	22 September 2020
Purpose of paper:	Report of Activity August 2019 to July 2020
Intended outcome:	For RKEC's general approval
Key points:	o Review and approval of applications - and changed protocol consequent on the COVID-19 lockdown. o Risk Management o Next Steps
Paper submitted by:	University Ethics Committee
Resource implications:	No
Equality & Diversity	An EIA has not been undertaken. Key purposes of the University Ethics Committee are 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.
Key contact(s):	Professor Philip Winn, SIPBS, philip.winn@strath.ac.uk
Date of production:	**08 September 2020**

UNIVERSITY OF STRATHCLYDE

UNIVERSITY ETHICS COMMITTEE

ANNUAL REPORT FOR ACADEMIC YEAR 2019-20

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 2019-20. 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 2019-20 Angelique Laverty, RKES Administrator, undertook the UEC Secretariat role and minutes were taken by Grace Murkett. 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, (August 2020) Vice-Conveners are:

- 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 22 September 2020.

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.

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 06 November 2019 (20 attendees) and on 20 January 2020 (14 attendees), under the Researcher Development Programme. The sessions were presented by Professor Philip Winn and included information on Data Management and GDPR.

Lay member Ms Shirley Andrews delivered a training session on applying for ethical approval at the annual Biomedical Engineering EngD Clinical Awareness Training day.

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 – and changed protocol consequent on the COVID-19 lockdown.

Until March 2020 UEC meetings proceeded as previously, on the first Thursday of every month. During the lockdown caused by the COVID-19 pandemic UEC did not meet face-to-face but did meet virtually using Zoom. UEC offered notes of guidance for the University.   (Available at https://www.strath.ac.uk/ethics/ and https://www.strath.ac.uk/coronavirus/staff/universityethicscommittee/. Copies are included as Annexes to this paper.)

A process was developed for fast-track review of applications relating to the pandemic that needed quick turnover. Reviews were done virtually and involved a smaller team of reviewers rather than the whole committee. The Chair normally led (with a Vice Chair substituting in case of unavailability), two academic members drawn from units appropriate for the application, a lay member supported by RKES staff.

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

before the meeting. The fast-track COVID-19 reviews ran on a rapid timeline: following receipt, the review team was formed and reviews done within 4 days.

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 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
Routine applications			
Approval			
Rejection			
Resubmit to UEC	5	3 *	0
Convener's action	42	6	36
COVID-19 fast track			
Approval			
Rejection			
Resubmit to UEC			
Convener's action	6	2 **	2
Total applications	53		

* two applications were withdrawn (UEC19/82 and UEC20/01).
** UEC20/21 was withdrawn and UEC20/46 was passed back to DEC.

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. 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.

16 NHS applications were submitted to or logged with the Ethics Team and 11 endorsed by the Convener on behalf of UEC during 2019-20, following favourable opinion from the NHS itself.

The Manager of UEC Secretariat in RKES approved sponsorship for 22 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 2019-20. 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 2019/20.

9.   University Ethics Committee Membership

Professor Philip Winn (SIPBS) is convener (since September 2018) and there are three Vice-Conveners: 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.

During the year, Professor Helen Marwick left the Committee and Dr Eleni Karagiannidou (School of Education) joined. 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 – including a new protocol consequent on the COVID-19 lockdown.

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. The insurance questionnaire and eRisk assessments created last year are being used successfully.

As part of the response to the COVID-19 pandemic, UEC was closely involved in creation of Guidance on the Manufacture of PPE at Strathclyde. This was done to make sure that any activity that had been independently initiated with the University was properly assessed and supported. A simple protocol was developed in

collaboration with University Senior Management and the University's National Manufacturing Institute Scotland team. Monitoring of activity was undertaken by the Ethics team within RKES.

11. Budget

At time of writing (September 2020) the budget for fiscal year 2020-21 has not 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

As noted last year, the Convener of UEC, Professor Philip Winn, on taking up the post realised that there was no immediate cause for concern and that committee members discharged their duties with considerable care and thoughtfulness. Examination of each application remains thorough and forensic.

Nevertheless, some refreshing of processes is required. To this end, the Convener undertook a series of consultations with DEC/SEC chairs and members. The outcomes of these conversations are reasonably consistent across the University and are grouped here thematically.

Forms
- Online – universal approval for developing an online application platform
- Forms refresh – universally recognized as needed
- Separate forms for UG, Masters, PhD, Staff?
- Better guidance – "What about …?" questions
- Pre-application checklists
- Better website materials relating to support and training
- A number of DEC/SECs use their own online application systems internally – need for UEC to review and assist / approve.

DEC/SEC/UEC relationships
- Better interactions DEC/SEC/UEC are needed
- Have DEC/SEC Chairs on a rotating panel for membership of UEC, called on rotationally
- Decision making – what's DEC/SEC, what's UEC?
- Management of conflict of interest within local reviews
- Local training – need to be seen by UEC
- Local processes – need to be seen by UEC
- Auditing material – UEC reviewing DEC/SEC decisions needs improving
- Clarity on devolved permissions from UEC to DEC
- Recommended DEC size in relation to application numbers

Data, methods, problems
- Governance / Stewardship / Ownership of data
- Data retention and storage – time and format; GDPR vs open data

- Online data collecting using focus groups creates issues of privacy and data protection.
- Social media needs better guidance in relation to research on it and recruitment through it
- International and other off site approvals lack clarity
- Relationships of methods and ethics is a common cause of friction
- Service level agreements – need better clarity and definition of what approvals these need.

The interruption of University activity through lockdown has delayed progress with further developments. Revision of the application forms is underway. This will be followed by reviews of the Code of Practice and reformation of the Committee (on which several members have been in post for long periods).

The goal in this is to make the University Ethics infrastructure function better as an enabler not be seen as a blocker. Conversations with unit heads indicates that there are cases where staff game the system to avoid ethical review, or at least to keep it in-house rather than submit to UEC. The creation of a better appreciation of the virtue and value of ethical review will require time but is a viable ambition.

ANNEX 1

UNIVERSITY ETHICS COMMITTEE

MEMBERSHIP AUGUST 2020

<u>Name</u>	<u>School/Department/Category</u>	<u>Date</u> <u>Appointed</u>
Convener		
Professor 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 Eleni Karagiannidou	School of Education	05.12.19
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)	Social Work & Social Policy and CELCIS	01.09.09
Professor James Windmill	Electrical & Electronic Engineering	01.06.10
External Members		
Ms Shirley Andrews	Retired Head of Training, Police Scotland	01.05.14
Mr James Wallace	Retired Pharmacist	01.08.13
Dr Barbara West (VC)	Retired GP	02.08.12
Lay Members		
Mr Nicholas Shearer	IT Consultant	01.03.14
Vacancy		

ANNEX 2: University Ethics Committee Covid-19 Guidance

GUIDANCE ISSUED 31 JULY 2020:

University Ethics Committee Covid-19 Guidance

Due to the current circumstances (Phase 3 of the Scottish Government's roadmap out of lockdown), research should be conducted using online or remote methods wherever possible.

New or restarting in-person face-to-face research or research involving travel must adhere to local or national laws and restrictions, such as those of the **Scottish Government**. Such research must also follow: **University Guidance**. If this is not possible, it must be postponed.

In-person face-to-face research can only start with:

o **New studies** – the submission and approval of an ethics application to the University Ethics Committee by emailing ethics@strath.ac.uk. The application should include an eRisk assessment which details the steps taken to mitigate risk of Covid-19.

o **Paused or approved-in-principle studies** – the submission and approval of an ethics amendment application.

If a researcher thinks that transmission of Covid-19 has occurred during the course of their research, they must inform Safety, Health and Wellbeing by emailing safety@strath.ac.uk and ethics@strath.ac.uk

This guidance will remain in place until the restrictions and additional considerations for research involving humans due to Covid-19 are no longer required.

It is expected that this means that this guidance will be in place throughout Phase 3 of the **Scottish Government's route-map out of lockdown**

This guidance will be reviewed again at the end of Phase 3. It may continue to be in place after this point, depending on what, if any, safeguards are required as part of Phase 4 and, if so, how these impact research involving humans and the associated processes such as risk assessment.

GUIDANCE ISSUED 2 April 2020:

Online and telephone interviews with participants
General guidance

1. Interviews can be carried out by video using the University's version of Zoom, or by telephone. Researchers should make any appointments directly and initiate calls promptly at the time of the appointment.
2. If permission is given through ethical review and by participants, research interviews can be audio-recorded using digital voice recorders or digital voice recording software. Storage, encryption and identity protection must be

specified. The Zoom platform encrypts all communication between the researcher's and client's computers.

3. Forms and questionnaires can be administered either by email or secure web-based applications such as Qualtrix.

4. Security of connections/settings and identity fraud are issues for telephone and video interviews. It requires researchers to verify the security of the connection/setting and the identity of the person they are speaking to at the beginning of sessions.

5. Emotional distress can be more difficult to detect and manage on video or by telephone than in face to face interactions. Attention must be given to vocal cues of emotional distress and strategies must be in place to mitigate it. Other participants may conversely be more rather than less open in telephone and video interviews, itself an issue to which researchers must be sensitive.

6. Participants involved in video sessions using the Zoom platform, might be self-conscious, seeing the thumbnail videos of themselves on screen. If this happens, the researcher will help them turn it off.

Transfer from face-to-face to online because of Covid-19

7. Some participants may feel disappointed or frustrated having to use online rather than face-to-face interviews. If this happens, they should be encouraged to speak to the researcher. If their concerns cannot be resolved they can be put on a waiting list until the crisis is over.

8. Some participants may find that their equipment (computer or mobile device) or internet service/mobile phone plan may not be adequate or secure enough for carrying out video sessions. This would most likely require them to take part by telephone, which might not be their preference. If their concerns cannot be resolved they can be put on a waiting list until the crisis is over.

9. Some participants may be in situations that do not allow private, confidential space for interviews. Researchers should work with the participant to help them make their space confidential and safe enough. If they were unable to do so, the participant would not be allowed to take part, although they could be put on a waiting list until the crisis is over.

10. If particular participant groups are unable to access or use internet/email-based forms copies of the relevant forms could be mailed to them for them to complete and mail back to the University, to be stored until the University re-opens. There is currently no evidence that coronavirus can spread by mail; however, following standard protocols: (a) All such mail would be set aside for at least 24 hours; (b) anyone opening mail would be required to refrain from touching their face and to immediately wash their hands.

Professor Philip Winn
Convener, University Ethics Committee
02 April 2020

GUIDANCE ISSUED 17 March 2020:

- **Where there is absolutely NO face-to-face contact between researchers and participants** there are unlikely to be new ethical issues arising as a result of Covid-19. Research should be able to proceed. If there are issues relating to Covid-19 the lead researcher must contact the Ethics Committee that approved the research (School/Department or University) to discuss any the additional risks or changes to the research protocol already approved.

- **Where there is face-to-face contact between researchers and participants**:

    o   studies that have not yet begun should be postponed.

    o   research that has already started which involves groups of people (whether vulnerable at-risk participants or not) must be put on hold.

    o   research that has already started with individuals rather than groups of people must be put on hold. However, where possible research could move to online alternatives (including *inter alia* Skype/Zoom, online questionnaires, postal questionnaires).

    Online interview methods have different ethical concerns compared to face-to-face in, for example, monitoring participants' state during the interview and how data are captured. The researcher must contact the Ethics Committee that approved the research (School/Department or University) to ask for a written change in protocol from a face-to-face to online engagement.

    The University Ethics Committee will consider any protocol change through its normal fast track process of conveners action.

    o   guidance must be sought from the University Ethics Committee (which will be guided as required by the University Safety Team) before restarting research.

    o   participants who have already been recruited should be informed that the research has been postponed and that they will be contacted again about a resumption of activity.

    o   if the research is sponsored by external funders they should be notified of any likely delay to completion.

For further information please contact:

Professor Philip Winn
Convener of the University Ethics Committee
philip.winn@strath.ac.uk

ANNEX 3: Fast track applications relating to research on Covid-19

University Ethics Committee Covid-19 Guidance: Fast track applications relating to research on Covid-19

An expedited review process can be used for new time critical studies relating to COVID-19 where there is a clear public health need to start research quickly. Projects that are not time critical must continue through the normal review process. We ask researchers to be mindful of this when considering the below guidance on expedited review.

UEC will use a two-tier expedited review process. Expedited reviews will only be considered for any new time critical studies relating to COVID-19 where there are proven public health grounds to commence:

1**. Submit a request for a 8 working day expedited review:**

This is the default process for any expedited review requests. Requests for this will be considered by the Chair of the University Ethics Committee

In order for any study to request an 8 working day expedited review the Chief Investigator must provide the following information:

1. What are the public health grounds for the study to be conducted?
2. What is the rationale for the study to be conducted at this time? Why can it not be conducted at a later time?
3. Where applicable, an explanation as to how the public health benefit outweighs the potential risk to the participants of contracting COVID-19 and what actions will be taken to mitigate this risk.
4. Where appropriate, a risk assessment considering the potential risk to the researcher themselves, signed off by the Head of Unit or Faculty. This is mandatory for any research that will involve travel or face-to-face interactions.

If your request is accepted your application review outcome is issued within 8 working days of receipt of a valid application.

2. **Submit a request for a fast track 4 working day expedited review process:**

Requests for fast track expedited reviews should only be made in exceptional cases where the urgency of the data collection commencement means that a 8 working day review turnaround would be detrimental to the public health implications of the research. For requests to be considered by the Chair of the UEC they must be supported by endorsement from the Chief Investigator's Head of Department or Dean of Faculty.

In order for any study to request a fast track 4 working day expedited review the Principal Investigator must provide the following information:

1. What are the public health grounds for the study to be conducted?

2. What is the rationale for the study to be conducted at this time? Why would a request for a ten working day expedited review be detrimental to the public health implications for the research?
3. Where applicable, an explanation as to how the public health benefit outweighs the potential risk to the participants of contracting COVID-19, and what actions will be taken to mitigate this risk.
4. Where appropriate, a risk assessment considering the potential risk to the researcher themselves, signed off by the Head of Department or Faculty.
5. For an expedited review within 4 working days the CI must also provide an endorsement from either their Head of Department or Dean of Faculty supporting the need for this level of expedited review.

If your request is accepted your application review outcome is issued within 4 working days of receipt of a valid application.

Researchers should send the answers to these questions to the UEC at ethics@strath.ac.uk. Please title the email "New Study relating to COVID-19" and your email will be prioritised.

If your request for an expedited review is accepted, you should state 'COVID-19' at the beginning of the title of your study when submitting the application.

Once your request is accepted, submission of a valid application is expected within 3 working days. Failure to submit within this timeframe will render the acceptance of expedited review null and void and a new request will have to be submitted.

If the request for expedited review is not accepted, the application will be reviewed at the next UEC meeting.

ANNEX 4: Guidance on the Manufacture of PPE at Strathclyde

<u>**GUIDANCE ISSUED ON 14 MAY 2020**</u>

University Ethics Committee Covid-19 Guidance: Guidance on the Manufacture of PPE at Strathclyde

1. This Guidance and Checklist is designed to support members of the University who wish to contribute positively to the creation of resources for use in the current pandemic.

2. It is important to the University that any work done is properly supported, guided and recorded to ensure the best possible outcomes for those creating resources and end-users of products.

3. The University recognizes that there are ethical risks in unregulated activity involving other professionals and members of the public. As such the University Ethics Committee have prepared the accompanying checklist to help ensure that anyone who has, is or intends to create products can do so safely and with minimal risk either to themselves or to end-users.

4. If you are engaged in the manufacture of products for healthcare use, whether in the NHS or another context, please make sure that you go through the checklist covering off each item.

5. **Enquiries can be made and completed checklists returned to** ethics@strath.ac.uk

6. **Useful resources …**

    -   **Guidance for New High-Volume Manufacturers of COVID-19 PPE** is available, which outlines information and processes for anyone wishing to make high volumes of Personal Protective Equipment (PPE). Whilst the guidance is not intended to cover small scale home production or manufacturing, its principles should be applied to these processes too.

        https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879796/Guidance-for-businesses-high-volume-manufacture-of-ppe-version-2.pdf

    -   In response to the European Commission's request and in association with CEN, the European Committee for Standardization, and CENELEC, the European Committee for Electrotechnical Standardization, BSI has made a series of **European Standards (ENs) for medical devices and personal protective equipment (PPE) used in the context of the current COVID-19 outbreak** available without charge on its website. This site is public, and the standards can be accessed without an institutional login to BSI Online.

        https://www.bsigroup.com/en-GB/topics/novel-coronavirus-covid-19/medical-devices-ppe/

    -   **The NHS Services Scotland Portal** has the latest Scottish supply needs and specification requirements for priority items and will automatically

enable your offer to be matched to these. Submitting details of your offer to the NHS Portal system will allow you to confirm the type of PPE you propose to supply, identify any standards to which it has been manufactured, and enable the NHS and Scottish Government teams to deal with it in the fastest possible time.

https://nhsnss.service-now.com/cv19_supply_offer

- **The University's National Manufacturing Institute Scotland (NMIS) team** are able to provide technical advice on manufacturing activities relating to or being conducted as part of the Covid-19 response. This team can be contacted by email at nmis-covid-response@strath.ac.uk

Professor Philip Winn
Convener, University Ethics Committee
14 May 2020