

SENATE RESEARCH ETHICS COMMITTEE

**Meeting No. 88 held on Thursday 14 February 2018
E214**

MINUTES

Attendance list

Composition		Membership	Initials	10/10/17	14/12/17	14/02/18	09/05/18	27/06/18
Chair		Professor Ron Douglas	RD	✓	✓	N/M		
Chair		Professor Peter Ayton	PA	N/M	N/M	✓		
Chairs of Local Research Ethics Committees (<i>ex officio</i>)	Business	Professor Paul Palmer	PP	A	✓	A		
	Health Sciences	Dr Nick Drey	ND	✓	✓	✓		
	Computer Science	Professor Jason Dykes	JD	✓	✓	A		
	Engineering	Dr Justin Phillips	JP	Abs	Abs	A		
	Law	Dr Jesse Elvin	JE	N/M	✓	A		
	Learning, Enhancement & Development	Professor Pam Parker	PPa	A	✓	A		
	International Politics	Dr Alexander Lanoszka	AL	A	A	A		
	Social Sciences	Dr Simon Susen/Dr Diana Yeh	SS/DY	SS	DY	SS		
Up to five members from the University's academic staff with expert knowledge		Dr Corinna Haenschel	CH	✓	A	✓		
		Dr Lorna Ryan (Deputy-Chair)	LR	A	✓	✓		
		Professor Alan Simpson	AS	A	✓	✓		
Up to three external independent members		Andrew Halper	AH	✓	✓	A		
		Dr Liz Wright	LW	N/M	✓	A		
Information Compliance Officer (<i>ex officio</i>)		Caroline Llewellyn	CL	✓	✓	✓		
Assistant HR Director, Health Service and Safety (<i>ex officio</i>)		Dr Christine Rajah	CR	✓	✓	A		
Up to two co-opted members		Professor Roland Petchey	RP	✓	✓	✓		
Up to two research students		Ylva Bäckstrom	YB	✓	A	✓		
In attendance	Research Governance & Integrity Manager (Secretary)	Anna Ramberg	AR	✓	✓	✓		

Key: ✓ = In Attendance A = Apologies N/M = Not a member R = Representative in attendance Abs = No apologies received

Observer: Mariah Loukou, Research & Enterprise Policy Officer

UNRESERVED BUSINESS

1. Apologies for absence

The Committee noted the apologies for absence and welcomed the new Chair, Professor Peter Ayton.

2. Declaration of conflict of interest

There were no conflicts of interest.

3. Minutes

The minutes of the meeting held on 14 December 2017 were approved.

4. Matters Arising

i. City Research Ethics Hallway Pages

The Committee noted that the launch of the research ethics webpages had been further delayed due to the web content officer being required to prioritise other projects. The Committee also noted that Marketing had

to sign off the pages before they could be launched and that Marketing would undertake an audit of the local REC research ethics pages to ensure consistency of content and information. It was hoped that the pages could be launched towards the end of March.

ii. Research Ethics Management Workflow System

The Committee received a verbal update on the progress of the procuring of an online research ethics management workflow system. The Committee noted that the shortlisted suppliers had been invited to give a presentation at the end of January and the preferred system had been selected. The business case had been updated and submitted to the RAMB meeting in February where it had been approved. It would now be submitted to the Finance Committee for final approval. Subject to final approval, it was estimated that the implementation would take up to three months, and that the system could be rolled out during the summer. A meeting was being arranged for Chairs and members of Committees to attend a demo and a Q&A session with the preferred supplier. In addition, a communication strategy would be put in place to ensure that the implementation of the system was well publicised before it went live.

iii. Departments of Engineering Research Ethics Committee

The Committee received a verbal update on the local Research Ethics Committee in Engineering and noted that a new Chair had been appointed, Professor Christopher Bruecker. AR would be meeting with Professor Bruecker and the Associate Dean for Research in SMCSE, Professor Panicos Kyriacou, in April to discuss the next steps in establishing appropriate policies and procedures.

vi. Terms of Reference, Composition and Membership

The Committee noted that no further developments had taken place since the last meeting. AR had prepared a paper to the Executive Committee (ET) with Deans about research ethics governance and planned developments but was unsure on when the paper would be discussed at ET. Once the paper had been discussed at ET, and any comments received had been incorporated, it would be circulated to the Committee for information.

v. Report on procedural issues

The Committee received a verbal report on the outcome of the potential procedural issues in relation to a previously reviewed project and noted that the applicant had not responded to the initial email requesting an explanation as to why the extension request had been submitted after the initial ethics approval had lapsed. The applicant had, after being prompted by AR, responded and apologised for what had been a misunderstanding on the applicant's part about the length of the approval: the applicant had thought the approval was for the length of the project, whereas it had in fact been for the length of the funding. PA had responded to the applicant and had expressed disappointment on behalf of the Committee and highlighted that, should this happen again, it would need to be escalated and could potentially lead to the misconduct procedure being instigated.

The correspondence is included in appendix 1.

The Committee agreed that a line would be added to the approval letter template emphasising that any researcher operating without approval or outside the terms of the approval was a breach of the ethics approval and would not be indemnified by City's insurance. It was noted that the new online system would have the capability of sending reminders before ethics approvals lapsed.

ACTION: AR to add the above to the approval letter template and circulate to local RECs.

Items for Information

5. To note Chair's Actions/Committee approval by distribution to approve the following research proposals since the last meeting:

There were no projects to note.

6. To note the request from the Committee for a resubmission of the following project:

There were no projects to note.

7. To note amendments/extensions to existing projects:

“SCAMPI: Self-Care Advice, Monitoring, Planning and Intervention co-design activities (Work package WP2)” by S Stumpf

8. To note that the projects listed below had been approved to carry out research at City or on City students/staff

There were no projects to note.

9. To note that the projects listed below had been approved by the Health Research Authority

There were no projects to note.

10. To note any outstanding projects

“Applications of direct spectrophotometric techniques in the visible and near infrared region to monitor shock by determining blood lactate and haemodynamic parameters in in vitro and in vivo studies on human volunteers” by P Kyriacou et al

11. To note any withdrawn projects

“Improved Healing by combining **Optical** and **Electrical Stimulation of Nerves (HOPEs)**” by I Triantis (Withdrawn by default due to no response to the Committee’s comments.)

Items for consideration – research involving human participants

12. To consider the following proposal from the Division of Optometry & Visual Sciences, School of Health Sciences

Lead: Professor Alan Simpson

“Myopia control using orthokeratology in a UK population” by M Nagra & E Senthan

The Committee received the above application. The Committee agreed that due to the nature of the proposal it was not appropriate for a City Research Ethics Committee to review this application. This was because City did not have the expertise to review therapeutic clinical trials and there were currently no policies or procedures governing therapeutic clinical trials in place at City. Accordingly, City was unable to ensure that appropriate safe systems were in operation, without which both the researchers and City would be legally exposed if anything were to go wrong during the trial. Furthermore, there was no evidence in the application that the investigators had the experience to undertake a clinical trial.

The Committee concluded a *No Decision* outcome. The Committee recommended that the researchers collaborated with a centre that had experience of running optometry therapeutic trials in children and applied for approval either through a HRA REC or through the partnering institution’s REC if appropriate.

Items for consideration – research involving animals

13. There were no items to consider.

Items for Discussion

14. Training for City REC members

The Committee discussed the training requirements for REC members, including annual training requirements (e.g. self-directed learning), attending other RECs as observers, and reflective discussions at REC meetings. The Committee noted the following in particular:

- There was a need to carry out spot checks on the effectiveness of procedures and standards adopted by the local RECs as per SREC’s ToRs. This included auditing local RECs and the decisions made by these Committees. It was agreed that members of SREC would attend local REC meetings, either copied into email deliberations if the meetings was virtual or in person as appropriate.

- The Committee would include a presentation of an ethical dilemma or paper on ethics at their meetings, when time allowed it. It was noted that the Cass REC was already doing this.
- It was proposed that all REC members attended an annual training at the start of each year. The training would include policies, legislation and legal aspects as well as ethical reasoning.
- There had been a discussion with one of the co-chairs at UCL about sharing best practice and for members to observe other RECs.
- It was proposed to extend the quality assurance of local RECs to PIs. This would take the form of a checklist that the PIs would complete, with questions such as 'the consent forms are stored separately from the other data'.

ACTION: PA to write a paper for the next SREC meeting.

15. Minutes of local Research Ethics Committees

The Committee noted the minutes of School and selected Departmental Research Ethics Committees:

- Cass Business School
- School of Health Sciences

The Committee noted that School of Health Sciences were currently advertising for new members to join the School REC.

16. Institutional Review Board

The Committee noted that any research conducted or supported by any U.S. federal department or agency was required to be reviewed as an Institutional Review Board under a Federal Wide Assurance. The assurance applied whenever this Institution become engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research was otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research should be conducted under a separate assurance.

Senate Research Ethics Committee maintained a Federal Wide Assurance of compliance with U.S. Department of Health and Human Services regulations for research involving human participants, and carried out ethical review and approval of projects which require FWA compliance. However, there was currently not a written process or a policy for such instances. There had only been two instances when research projects had been conducted or supported by any U.S. federal department or agency, but a policy for how SREC dealt with such instances would need to be produced.

ACTION: AR to write a policy by 2018/19.

17. Any Other Business

There was no other business.

18. Date of next meeting:

Wednesday 09 May 2018, 2pm, AG01

Wednesday 27 June 2018, 2pm, AG01

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