UNIVERSITY OF HERTFORDSHIRE HIGHER EDUCATION CORPORATION

ETHICS COMMITTEE FOR STUDIES INVOLVING HUMAN PARTICIPANTS

Minutes of the meeting of the Ethics Committee for Studies Involving Human Participants held on 23 October 2019.

PRESENT: Professor Barry Hunt (Chair)

Rev Dr Allan Smith     Dr Simon Trainis     Michelle McPhail
Dr Colin Blankfield    Dr Tim Parke        Catherine Rendell

IN ATTENDANCE:

Ian Hanahoe           Abi Tomlinson       Leire Caselles Vallejo

APOLOGIES:

Dr Susan Grey         Professor Constantine Sandis  Lianne Oosterbaan
Dr Rosemary Godbold   Dr Brendan Larvor    Alex Hall

1  MEMBERSHIP

1.1 Category 3: Five (5) members, at least two (2) of whom will normally be external to the University, drawn from a range of disciplines as agreed between the Vice-Chancellor and the Chairman of the Ethics Committee, and to include a moral philosopher and a medical practitioner

The Committee noted vacancies for a Social Scientist and a Lawyer in this category. Discussions were underway with the University of Law with the view to appointing a new Lawyer member.

1.2 Category 6: The Vice-Chairmen of Ethics Committees with Delegated Authority:

The Committee noted that Dr Roberto Gutierrez, from Psychology and Sport Sciences, had been proposed as interim Vice-Chair while Dr Amanda Ludlow, current Vice-Chair, was on maternity leave and that his candidacy would now be considered by the Chair.

1.3 Officers in attendance

1.3.1 The Committee noted that Ian Hanahoe, Data Protection Officer, and Abi Tomlinson were in attendance as the nominees of the Director of Legal and Compliance Services and University Solicitor (Secretary to the Committee).

1.3.2 The Committee further noted that Abi Tomlinson would take over as acting Data Protection Officer after Ian Hanahoe’s imminent departure from the University. The Committee thanked Ian Hanahoe for his help and guidance during his time as Data Protection Officer, particularly through the implementation of the new GDPR legislation since May 2018, and wished him all the best for the future.

1.4 Current membership

The Committee noted its amended membership, subject to confirmation of Dr Gutierrez’s appointment as Vice-Chair of the Health, Science Engineering and Technology (HSET) Ethics Committee with Delegated Authority (ECDA).

(Agenda Paper 2.3, refers.)
The Minutes of the meeting of 1 May 2019 were confirmed and signed.

(Confidential Agenda Paper 3, refers.)

**MATTERS ARISING (NOT TAKEN ELSEWHERE)**

3 **FAQ - COLLECTION OF DATA BY STUDENTS WHILST ON PLACEMENT - MINUTE 109, REFERS**

3.1 The Committee considered an amended version of the FAQ and advice from Dr Liz Gormley-Fleming, Associate Director Academic Quality Assurance-Degree Apprenticeships, in respect of Degree Apprenticeship students, and from Claire Crux, Assistant Head of Careers and Employment.

3.2 Members agreed that the last paragraph of the proposed FAQ text required amending to eliminate confusion. The current text led to conclude that it was acceptable to collect data before obtaining ethical clearance. The text should clarify that the paragraph referred exclusively to re-using data that had been collected for a different purpose, for example, as part of the applicant’s employment duties. The paragraph would be amended accordingly, and the new FAQ text circulated to members electronically to seek approval for publication.

3.3 Members discussed the ethical issues arising from re-using data collected for a different purpose, particularly where participants had not given consent for their data to be re-used or where it was impractical or impossible to seek renewed consent. Members noted that anonymised data was outside of Data Protection regulations, however, ethical considerations remained.

3.4 The Committee decided that the decision of giving ethical clearance for the re-use of data should continue to be considered on a case by case basis. The issues of consent, permission, potential harm, etc. would be considered as part of the review process.

(Confidential Agenda Paper 4, refers.)

4 **SYNCHRONISATION OF FORM EC5 AND THE LMS RISK ASSESSMENT - MINUTE 110.1, REFERS**

4.1 The Committee received an oral report from the Chair of the HSET ECDA, Dr Simon Trainis.

4.2 Dr Trainis explained that, currently, if the LMS risk assessment was considered to have covered everything, an ‘EC5 Harms, Hazards and Risks Form’ was not being requested from the applicant. When the LMS risk assessment did not cover everything, the applicant was asked to complete an EC5 form. This seemed to be working well for the applicants and the ECDA.

4.3 Dr Trainis had continued to pursue the synchronisation of Form EC5 and the LMS risk assessment, however, the School staff involved in the discussions had left the University and progress had stalled.

4.4 The Committee agreed that it would be ideal to have just one form to address all risks, however, given the difficulty in achieving this and the fact that the current process was working well, the Committee decided that the matter of a single risk assessment form would no longer be pursued.
OVER-VOLUNTEERING IN SPORTS SCIENCE CLASS PROTOCOLS - MINUTE 110.3 AND NOTE 8, ETHICS CHAIRS TERMLY MEETINGS, 8 OCTOBER 2019, REFER

5.1 The Committee considered a response from Ali Cain, Deputy Dean, School of Life and Medical Sciences, to a query from Dr Simon Trainis concerning the Sports Science ethics protocols and how participation would be monitored to avoid over-volunteering of participants.

5.2 Members acknowledged that the issue of over-volunteering was taken into consideration and addressed as part of the consent process. However, it was agreed that the health screening form should contain a question for participants about any involvement in other studies so the issue of burden could be assessed by the researcher. Dr Trainis would respond to the Deputy Dean accordingly.

Minutes 5.3 to 5.4 are confidential and available to Members and Officers in attendance only.

(Detail: Confidential Agenda Paper 6, refers.)

DR AMANDA LUDLOW’S OPEN ACCESS QUERY - MINUTE 112.2 AND NOTE 13, ETHICS CHAIRS TERMLY MEETINGS 8 OCTOBER 2019, REFER

The Committee noted that appropriate wording for inclusion in the participant information sheet and consent form in relation to open access had been considered at the last Ethics Chairs termlly meeting and work was in progress.

UPR RE02 RESEARCH MISCONDUCT AND SAMP PANELS - MINUTE 88.3, REFERS

The Committee noted that the Director of the Doctoral College, Dr Susan Grey, was currently analysing the interaction between UPRs RE01 ‘Studies Involving Human Participants’ and RE02 ‘Research Misconduct’ and would report on her findings at a future meeting. Amendments to UPR RE02 were expected to clarify the disciplinary process for research students suspected of breaching UPR RE01.

INTI CLASS PROTOCOLS

UPDATE ON INTI CLASS PROTOCOL APPLICATIONS - MINUTE 105.3, REFERS

Minute 8 is confidential and available to Members and Officers in attendance only.

ETHICS QUESTION ON RE-VALIDATION CHECKLIST - MINUTE 105.3.3,I, REFERS

The Committee received an oral report from the HSET ECDA Chair, Dr Simon Trainis, who confirmed that a question about activities requiring ethics approval was still included in the validation agenda document.

RESPONSE FROM THE DIRECTOR OF ACADEMIC QUALITY ASSURANCE - MINUTE 105.3.3,II REFERS

10.1 The Committee considered the response from the Director of Academic Quality Assurance, Dr Frank Haddleton, to the Chair regarding the issue of ensuring that ethics regulations were fully adopted by collaborative partners.

10.2 The Committee noted assurances that ethics regulations and procedures would be added as an item in the next Collaborative Partnership Leaders Symposium.

10.3 The Committee also noted that the Collaborative Operational Delivery Plan (CODP) template did include compliance with ethics regulations UPR RE01 as a mandatory function to be discussed with partner organisations.
10.5 The Committee further noted that the Annual Monitoring and Evaluation Report (AMER) template did not include information regarding ethics approval for studies involving human participants. It was agreed that there would be benefit in the AMER specifying whether compliance with ethics regulations was monitored and whether there had been any breaches.

10.6 The Committee agreed that the Director of Academic Quality Assurance, the Deputy Director of Academic Quality Assurance and the Associate Director of Academic Quality Assurance would be invited to the next Chair/ECDA Chairs termly meeting to discuss how to ensure that partner organisations were fulfilling their obligations in relation to the ethics regulations.

CLERK

(Confidential Agenda Paper 11, refers.)

MATTERS REFERRED FROM ECDAS

11 NEW FAQ - DEALING WITH ADULT VULNERABLE GROUPS - NOTE 2.3, ETHICS CHAIRS TERMLY MEETINGS, 3 APRIL 2019, REFERS

11.1 The Committee considered a new FAQ, proposed by the HSET ECDA, concerning the dealing with adult vulnerable groups in a study.

11.2 The Committee agreed the following amendments to the text:

(a) the definition of vulnerable adults should be moved to the beginning of the text;
(b) it should be specified that the definition of vulnerable adults in a research context was far wider than the definition of the Mental Capacity Act and that individuals in prison were also considered vulnerable;
(c) the word ‘property’ would be substituted with ‘characteristic’;
(d) the need to consider the effect of the study coming to an end on both the researcher and the vulnerable participants would be added.

11.3 The Committee agreed that the amended text would be circulated electronically to members for approval.

CLERK

(Confidential Agenda Paper 12, refers.)

12 SSAH ECDA - ANNUAL REPORT 2018-19

12.1 The Committee received the SSAH ECDA Annual Report 2018-2019 from the SSAH ECDA Chair, Dr Tim Parke.

12.2 The Committee noted that 70 per cent of applications had failed to pass the ‘admin check’, meaning that the application forms had not been completed correctly on first submission. Applicants may have failed to answer all relevant questions, attach required documents, annotate the consent form and/or the participant information sheet correctly, among other things. This generated a significant amount of administrative work for the ethics administrators and caused delays in the processing of applications.

Minute 12.3 is confidential and available to Members and Officers in attendance only.

12.4 The Committee also noted that, for the first time, the report included information on training provided by the ECDA.

12.5 Members agreed that the section of the report regarding administrative support for the SSAH ECDA should clarify that this resource was shared with the HSET ECDA.

(Confidential Agenda Paper 13, refers.)
13 HSET ECDA - ANNUAL REPORT 2018-19

13.1 The Committee received the HSET ECDA Annual Report 2018-2019 from the HSET ECDA Chair, Dr Simon Trainis.

13.2 The Committee noted that the percentage of applications for the HSET ECDA that did not pass the admin check on first submission was also very high at 76 per cent.

13.3 Peaks and troughs in applications during the academic year were also noted, as well as the breakdown per School, with LMS representing 77 per cent of all applications.

13.4 The Committee agreed that the HSET ECDA Annual Report would also start reporting on training conducted.

*Minute 13.5 is confidential and available to Members and Officers in attendance only.*

(Confidential Agenda Paper 14, refers.)

**OTHER MATTERS**

14 ANNUAL REPORT TO THE ACADEMIC BOARD 2018-19

The Committee considered and approved the Annual Report to the Academic Board for 2018-2019.

15 RISK

There were no risks inherent in the matters dealt with by the Committee during the meeting that were not discussed when the item concerned was taken.

16 PEOPLE DEVELOPMENT

The Committee agreed that the issue of using vulnerable groups as participants should be addressed as part of the ethics reviewer training.

17 CLERK’S REPORT

The Committee received the Clerk’s report. The Clerk's report ensured the completeness of the Committee’s record of business.

(Confidential Agenda Paper 18 and Minutes 17.1 to 17.8, refer.)

17.1 Academic Board Standing Orders

The Committee noted the Standing Orders of the Academic Board, which could be found at the following link:


17.2 Terms of Reference and Composition

The Committee noted its Terms of Reference and Composition, which could be found at the following link:

https://www.herts.ac.uk/__data/assets/word_doc/0017/234233/2019-04-17-ECSIHP-Constitution.doc
17.3 **Annual Communication to staff and students**

The Committee noted the annual communication to be sent to staff and students via UHQ and StudyNet.

*(Part 2, Confidential Agenda Paper 18, refers.)*

17.4 **Chair/ECDA Chairs termly meetings**

The Committee noted the Notes of the Chair/ECDA Chairs termly meeting of 8 October 2019.

*(Part 3, Confidential Agenda Paper 18, refers.)*

17.5 **Research Committee**

The Committee noted the Minutes of the Research Committee meeting of 23 May 2019.

*(Part 4, Confidential Agenda Paper 18, refers.)*

17.6 **HSET ECDA Minutes**

The Committee noted the Minutes of the HSET ECDA meeting of 8 May 2019.

*(Part 5, Confidential Agenda Paper 18, refers.)*

17.7 **SSAH ECDA Minutes**

The Committee noted that the meeting of the SSAH ECDA of 15 May 2019 had been cancelled due to insufficient business.

17.8 **Schedule of meetings 2019-2020**

17.8.1 **Ethics Committee**

- 1400 hours, Wednesday 23 October 2019, Woburn Room, MacLaurin Building
- 1400 hours, Wednesday 12 February 2020, Woburn Room, MacLaurin Building
- 1400 hours, Wednesday 29 April 2020, Woburn Room, MacLaurin Building

17.8.2 **Health, Science, Engineering and Technology ECDA**

- 1400 hours, Wednesday 9 October 2019, Governors’ Suite, College Lane Campus
- 1400 hours, Wednesday 26 February 2020, Governors’ Suite, College Lane Campus
- 1400 hours, Wednesday 6 May 2020, Governors’ Suite, College Lane Campus

17.8.3 **Social Sciences, Arts and Humanities ECDA**

- 1400 hours, Wednesday 2 October 2019, R023, Law School, De Havilland
- 1400 hours, Wednesday 29 January 2020, Woburn Room, MacLaurin Building
- 1400 hours, Wednesday 13 May 2020, Woburn Room, MacLaurin Building

18 **EMERGENCY BUSINESS**

There was no emergency business.

19 **DATE OF NEXT MEETING**

Wednesday, 12 February 2020 from 14:00 hours - Woburn Room - MacLaurin Building.

Items for the Agenda should be notified to the Clerk, Leire Caselles Vallejo (*e*-mail l.caselles-vallejo@herts.ac.uk) by 22 January 2020 and reports submitted by 29 January 2020.