

UNIVERSITY RESEARCH ETHICS COMMITTEE

MINUTES

Meeting held 24th April 2024

Present: Lesley Braiden (LB), Dr Jan Deckers (JD), Dr James Frith (JF), Professor Matthew Grenby (MG, Chair), David Hill (DH), Louise Jones (LJ, Secretary), Chirag Kumar (CK), Susanne Lewis (SL), Dr Jessica Martin (JM), Kate McGill (KM), Dr Jane Midgley (JM), Dr Dana Ofiteru (DO), Lorna Taylor (LT), Professor Simon Woods.

Apologies for absence: Shah Yaseen Ali, Dr Eve Cosgrave, Mike Davison, Professor Violetta Hionidou (VH), Professor Tina Sikka (TS), Professor Candy Rowe.

1. PRELIMINARY BUSINESS

1.1 Welcome

Noted: the Chair welcomed members to the annual Committee meeting and noted the apologies. It was also noted that there were a number of new members:

- Dr Jane Midgley – *academic member of staff*
- Emeritus Professor Simon Woods – *lay member*
- Lesley Braiden – *lay member*

The Postgraduate Officer from the Student's Union, Chirag Kumar, attended the meeting in place of the President. Dr James Frith was also in attendance as the new Deputy Chair in the Faculty of Medical Sciences.

1.2 Minutes

Received: the minutes of the previous meeting held on 20th April 2023 (Document A).

Noted: the minutes were accepted as an accurate record.

1.3 Matters arising from the Minutes

Received: a progress update on the actions arising from the previous meeting (Document B).

Noted: all of the actions from the previous meeting have been completed.

1.4 Terms of Reference

Received: the draft Terms of Reference (Document C).

Noted: the central Research Strategy and Development (RSD) service changed to Research and Innovation (from 1st April 2024). All references to Research Strategy and Development have therefore been removed.

1.5 Membership List

Received: the current membership for 2023-24 (Document D).

Noted: All references to Research Strategy and Development have likewise been removed. Mike Davison's membership expires in 2024 and Prof. Violetta Hionidou's membership is due to expire in 2025. This will be noted with Nominations Committee to begin the process of recruiting replacements. **(Action: LJ)**

2. REGULAR REPORTS

2.1 University report

Received: the annual report from Research and Innovation (Document E).

Noted: overall, the **ethics application data** for academic year 2022-23 represents a similar profile to 2021-22, although there was an increase in the number of applications received by the Faculty of Medical Sciences (FMS) (from 168 to 192), compared to a decline in applications received by the Faculty of Science, Agriculture and Engineering (SAGe) (from 60 to 36). The **average turnaround time** across the three Faculties has increased slightly from 18.1 days to 20.8, although a few significant outliers were identified. It was also noted that the recruitment and training of new Committee members had had an impact on turnaround times.

As part of the Committee's annual assurance processes, an **annual ethics audit** is conducted by the central Research and Innovation team based on a sample of low-risk projects. From this sample, a number of queries were identified, which Faculty Research Ethics Committees were asked to investigate. In one case, it was confirmed that appropriate ethical approval had been granted. In the other three cases, external ethical approval had been granted but the researcher had not confirmed this by completing the University's online ethics form and uploading a copy of the approval document. Therefore a learning need was identified.

A number of new developments were noted in relation to **central guidance, support and training**. Including a new Ethics Guidance Note on Impact and Engagement Activities and a Template Privacy Notice for research. An online Responsible Research Innovation (RRI) toolkit has also been developed to promote awareness of the unintended consequences of research and innovation on people, places and the environment in relation to bringing a new product or service to market. This includes a new self-assessment tool to help researchers identify potential RRI considerations, which can be used to support funding applications (where appropriate). Regular face-to-face workshops on Good Research Practice have also been delivered to PhD Supervisors and Professional Service colleagues. Further workshops will be delivered from Summer 2024 as part of the Research Leads Programme.

It was noted that the implementation of the new **Research Ethics Policy** was delayed due to the required amendments to the University's online ethics form. Due to technical difficulties with the current system (Lime Survey), it has not been possible to amend the structure of questions without corrupting the integrity of the underpinning workflows. This issue will be addressed through the investment of a replacement Ethics System. In the meantime, defence and security research considerations have been incorporated into the section on Environment and Responsible Research Innovation.

A new section on **defence and security research** has also been added to the University's online ethics toolkit. Over the next 6 months, the central Research and Innovation team will provide support for the review of these types of activities. This will enable the Research and Innovation team to create a central record of defence and security research activities and develop case studies and other training resources.

Following the initial market research, the University has approved the purchase of a **replacement Ethics System**. Work is now underway to complete the procurement documentation and a Steering Group will be established to lead the delivery of the project. The University aims to have a new Ethics System in place by Autumn 2024, although this will depend on the procurement, contract and customisation processes. An update will be provided to key stakeholders on delivery timescales once a preferred supplier has been formally identified. Representatives from the Ethics Sub Committees will be invited to participate in a review of the wording of the current questions and workflows. Work will also be completed on developing systems guidance and training to support the implementation of the new system. **(Actions: LJ)**

A full-scale review of the information, guidance materials and template documents available on the University's **online ethics toolkit** will also be undertaken by the Research and Innovation team in consultation with Ethics Sub Committees. The University's research governance webpages will also be updated to include a new Human Tissue Governance Toolkit. **(Actions: LJ)**

Received: a paper outlining Newcastle University's approach to working with Defence and Security sector organisations (Document M).

Noted: the aim of the document is to raise awareness of the existing internal procedures for scrutinising proposals and the different considerations which form part of the decision-making processes. It was noted that all activities involving organisations in the defence and security sector would require University Executive Board (UEB) approval moving forward.

2.2 Faculty reports

(a) Faculty of Humanities and Social Sciences

Received: the annual report from the Faculty of Humanities and Social Sciences (Document F).

Noted: Dr Sara Ganassin has taken over the role of Committee Chair from Dr Ilke Turkmendag. A total of six new Ethics Convenors have also been appointed over the last year. Changes in the Committee membership resulted in an increase in average turnaround times from 9.8 to 13.6 days, although the Faculty has now adopted the system of sending out diary invites to remind Ethics Convenors of deadlines. It is also hoped that the implementation of a new Ethics System will significantly streamline the process for local co-ordinators and reviewers. The development of a new e-learning module on research ethics linked to the University's 'Essentials' programme was proposed to support awareness raising. It was agreed that this would be discussed in further detail in relation to item 3.1(a).

(b) Faculty of Medical Sciences

Received: the annual report from the Faculty of Medical Sciences (Document G).

Noted: Dr James Frith has recently been appointed Vice Chair following the departure of Dr Jenny Read. A total of 19 new reviewers were appointed in 2022/23, increasing the total number of reviewers to 71 within the Faculty of Medical Sciences. This includes Undergraduate Sub Panels which specifically review Psychology and Pharmacy student projects, as well as a Postgraduate Taught (PGT) Panel, which provides a proportionate review of PGT student projects. It was noted that there was a frequent turnover of reviewers in the Faculty. JD offers one-to-one or group inductions for new reviewers. Two informal committee meetings were also held over the last year for the purposes of training.

A number of requests for additional support were noted during the meeting. Some of the responses to the issues raised were provided off-line to enable sufficient time to discuss other items on the agenda. For completeness, this information has been incorporated into the minutes, but is presented in italics.

- i) **Automatic assessment of risk:** it was noted that there are still concerns around whether the automatic approval of low-risk projects is appropriate.

The initial automated assessment of risk was built into the University's ethical review process to reduce the need for the manual assessment of the level of risk. Based on the data for 2022/23, a total of 1,695 projects involving human participants were automatically approved as low risk (755 in FMS, 436 in HaSS, 504 in SAgE). Therefore, the manual review of all projects involving human participants would have a significant impact on the workload of Faculty Research Ethics Committees and application turnaround times. Due to the lack of a workable alternative, the University is looking to invest in a replacement Ethics System which continues to provide an initial automated assessment of the level of risk. However, flexibility will be built into the system regarding how the University chooses to define "high" and "low" risk. This matter will be addressed through the review of the wording of questions on the University's ethics form and the implementation of the new Ethics System. **(Action: LJ)**

- ii) **Researcher safety:** a request for further guidance was noted, alongside a proposal to adopting a formal "buddy" policy for researchers working with human participants.

It was noted that the Occupational Health and Safety Office provide a range of guidance documents including a link to the Social Research Association's Code of Practice for the Safety of Social Researchers and a Lone Worker Risk Assessment template. A 'Preventing Harm in Research' framework document is currently being drafted to promote further awareness of relevant University policies, procedures and guidance. The draft document will be circulated to the Committee for comment. **(Action: LJ)**

- iii) **Use of gatekeepers:** additional guidance was requested, including guidance for colleagues passing on collected data.

The wording of the section on gatekeepers on the University's online ethics toolkit was updated following the last Committee meeting. Therefore further clarification is requested on what additional guidance is needed. **(Action: JD / PF / SL)**

A gatekeeper is defined in the University's Research Ethics Policy as a third party who is used to access potential research participants. Other legal and ethical considerations apply to sharing of research data, which are defined under the General Data Protection Regulation (GDPR). Guidance for Data Controllers on the sharing of personal data forms part of the University's mandatory GDPR training. The Information Governance team can also provide guidance in response to specific queries (email: rec-man@ncl.ac.uk).

- iv) **Potentially harmful procedures:** further clarification was sought on the wording of the sub-level question on working with human participants on the University's online ethics form regarding whether the study involves 'invasive, intrusive or potentially harmful procedures of any kind'.

The sub-level question only applies to procedures carried out human participants which may have potential side effects. A list of different types of procedures that this may apply to is also provided in the question text. The University's default position is that all projects involving human participants should be reviewed by a Faculty Research Ethics Committee, apart from studies in which interactions with participants are limited to those most people would regard as trivial. For example, asking uncontentious questions in surveys or observing people undertaking normal activities. If there is any doubt whether the procedure may be harmful,

the applicant should tick 'Yes' and the application forwarded for further review by a Faculty Research Ethics Committee. However, Ethics Sub Committees will be invited to participate in the review of the wording of questions on the University's ethics form prior to the implementation of the new Ethics System.

- v) **Sensitive topics:** additional guidance was requested on the discussion of sensitive topics and the sharing of sensitive data.

The discussion of sensitive topics would also indicate the need for further review by a Faculty Research Ethics Committees. Although two examples of sensitive topics are provided in the wording of the question (sexual activity or drug use), additional examples could be added to the list if required. This will be picked up as part of the review of the wording of questions on the ethics form as well as the review of the guidance available on the University's online ethics toolkit. Guidance for Data Controllers on the sharing of sensitive and personal data forms part of the University's mandatory GDPR training.

- vi) **Supervisor sign-off:** it was noted that mandatory supervisor sign-off should be a requirement in the new Ethics System.

It was noted that supervisor sign-off had already been identified as a key requirement during the initial planning phase. As part of the procurement process, potential suppliers will be asked to demonstrate how their product meets this requirement.

- vii) **Research data:** clarification was also requested on research data storage and retention requirements.

The University recommends that research data is stored for 10 years, although specific funder terms and conditions may apply. These expectations are set out in the University's Research Ethics Policy and Research Data Management Policy. Further guidance and support on developing a Research Data Management Plan is available from the Library (email: rdm@ncl.ac.uk).

- viii) **Complaints procedures:** additional guidance is need on where people should complain about a study as a number of different email addresses are being used.

Section 7.5 of the University's Research Ethics Policy states that 'a primary contact should be identified within the project team who can be approached regarding questions, comments and complaints.' The Research and Innovation team may also be listed as a secondary contact for complaints (email: research.integrity@ncl.ac.uk). A flow chart illustrating the complaints process is provided at Appendix 3.

Faculty Research Ethics Committees should therefore review the complaints procedures outlined on Participant Information Sheets to ensure that an appropriate primary / secondary contact is being used.
(Action: FMS / HaSS / SAgE)

(c) Faculty of Science, Agriculture and Engineering

Received: the annual report from the Faculty of Science, Agriculture and Engineering (Document H).

Noted: the Faculty has now identified Ethics Convenors in each School, who have all been provided a formal workload allocation. School Research Managers have also been formally invited to join the Committee to promote joined-up working. Although average turnaround times have increased over the last year (24.5 to 34.8 days), three significant outliers were identified. Meeting invitations continue to be used alongside email reminders regarding review deadlines. General

awareness of the ethical review process within the SAgE Faculty was identified as a key issue. As a result, the Chair has initiated a series of School meetings. Central support was requested for the preparation of local training materials. **(Action: DO / KM / LJ)**

2.3 AWERB report

Received: the annual report from the Animal Welfare Ethical Review Body (AWERB) (Document I).

Noted: the report provided a summary of operations over the last year, including data on the number of procedures involving animals at Newcastle University. This data is also reported to the Home Office on an annual basis, as per the terms of the University's Establishment Licence. Following her appointment as Chair in January 2023, JM has completed a full-scale review of the University's compliance with UK legislation on animals and introduced measures to increase engagement with the AWERB. To promote good practice, JM is also a member of the University's Farm Management Board.

During the last Committee meeting, JM raised a concern regarding the management of the commercial pig unit at Cockle Park Farm. Following this, an internal inspection visit was held and the University took the decision to close down the unit. A summary of the areas of concern and recommendations was presented in the AWERB report, although there is still an action outstanding on the School of Natural and Environmental Sciences to produce a report on lessons learnt. The Committee noted the importance of this report in relation to future developments on University Farms, including a potential new commercial pig unit. It was agreed that this matter would be picked up outside the meeting through discussions with the Establishment Licence Holder. **(Action: JM / DH / MG)**

3. OTHER BUSINESS

3.1 Items for Discussion

(a) Participation in external research projects

Received: a discussion paper on external research projects (Document J).

Noted: University colleagues and students may occasionally be invited to participate in external research projects. Although these studies are not conducted on University premises, they may be advertised via social media, posters or leaflets on campus. Information about external research projects may also be circulated via internal mailing lists following direct contact with a specific department. An individual who can provide access to potential research participants is referred to as an internal 'gatekeeper'.

It is generally accepted that participation in external research projects will be on a voluntary basis, and therefore a personal choice for individual colleagues and students. And that if an individual chooses to take part in a study, any questions, comments or concerns would be addressed to the Lead Researcher or the sponsor using the contact details provided on the study documentation. It is also accepted that anyone is approached to act as an internal gatekeeper should satisfy themselves that the protocol meets the University's ethical standards and that ethical approval has been granted. However, the lack of formal guidance could represent a potential safeguarding issue for University colleagues and students.

The Committee agreed that it would not be possible to implement a policy due to the lack of central oversight of social media platforms or posters and leaflets displayed around the University's campuses. It was also agreed that further review / approval by Faculty Research Ethics Committees was not appropriate as this would imply accountability for the study. However, the Committee did feel that formal guidance was needed to clarify that the University was not liable for the conduct of external research projects nor the conduct of external researchers. A University

level statement will therefore be produced setting out the expectations of external researchers based on the models at Oxford and Sheffield universities. **(Action: LJ)**

(b) Definition of “animals” in research and innovation projects

Received: a proposed policy amendment on working with animals (Document K).

Noted: to avoid confusion within the research community, internal comms to promote the new Research Ethics Policy with regard to animals has been delayed to enable Committee discussion of the proposed policy amendment.

The current wording of the policy defines animals as non-human invertebrates, cephalopods (e.g. octopus and squid) and decapod crustaceans (e.g. lobster and crab). This definition is based on the legal protection of animals in research under the Animals (Scientific Procedures) Act 1986, as well as the recent inclusion of decapod crustaceans as sentient beings under the Animal Welfare (Sentience) Act 2022. Other invertebrates are not currently protected by law, although the AWERB have advised that UK legislation may be updated. As a result, the University’s policy should be updated reflect a broader definition of animals (e.g. all non-human vertebrates and invertebrates). The amendment would also provide the AWERB greater oversight of activities involving animals across the University, and enable the Committee to respond more quickly to Freedom of Information (FOI) requests.

It was noted that the proposed amendment would potentially have an impact on the research communities in several academic units, including the School of Natural and Environmental Sciences (SNES) and the Biosciences Institute, where research activities involving invertebrates have previously been approved as low risk. It was acknowledged that researchers in these areas may be concerned about the additional ethical requirements and the longer approval timescales. However, it was noted that, based on a review of application data from 2022-23, only 21 projects which were automatically approved as low risk would have been flagged for further review by the AWERB if a wider definition of ‘animals’ was adopted. Therefore the additional volume of work for the AWERB is considered to be manageable, and additional members could be appointed if required. It was also agreed that an expedited review should be carried out for activities involving invertebrates.

The Committee approved the proposed amendment in principle on the basis that further consultation would be carried out with the research communities in SNES and the Biosciences Institute on the practical application of the policy and support requirements prior to implementation. **(Action: JM / LJ / SL)**

(c) Ethics training requirements

Received: a discussion paper on ethics training requirements (Document L).

Noted: the purpose of this paper is to raise awareness of the range of training, tools and resources available to University colleagues and students to support good practice in research ethics. These resources include policies, guidelines, webinars, videos, workshops and e-learning programmes. The University’s online ethics toolkit also provides detailed guidance on potentially high-risk activities. Information on these resources is available to view on the University’s Research Integrity webpages and will be linked to the new ‘Research Space’ platform in due course. Although capacity within the central Research and Innovation team to deliver in-person training is limited, standard presentation slides have been developed which can be downloaded and use as a local training tool.

As a need to increase awareness and engagement was identified in each of the three Faculty and AWERB reports, the Committee was asked to consider what additional ethics training is required and the means of delivering it. Following the suggestion from the HaSS Faculty, it was agreed that a short e-learning programme on research ethics should be developed and the possibility of it being embedded in the University 'Essentials' programme should be investigated. **(Action: LJ / DH)**

The Committee will also feed into the current review of PhD Supervisor training to determine how research ethics can fit into this scope of work. **(Action: LJ)**

From May 2024 onwards, LJ will deliver a new workshop on 'Ethics and Responsible Research Innovation' as part of the Smart Support Programme for Professional Service colleagues . It was agreed that the workshop will also be offered to an academic audience and delivered 3 or 4 times a year through the University's Open Learning Programme. **(Action: LJ)**

3.2 Date of Next Meeting

The next meeting will be held on 29th April 2024 at 10:00 am. The venue will be confirmed as soon as possible.