

MINUTES OF THE MEETING OF THE OPEN RESEARCH INTEGRITY AND ETHICS COMMITTEE HELD ON 03 NOVEMBER 2020 VIA VIDEOCONFERENCE AT 10:00 AM

Present: Professor Kim Graham (Chair), Dr Rhian Deslandes, Professor William Evans, Professor Debbie Foster, Professor Kerry Hood, Dr Dawn Knight, Dr Michael Lewis, Professor Adrian Porch, Judge Ray Singh, Professor Phil Stephens, Dr Jessica Steventon, Professor Andrew Westwell and Dr Chris Whitman.

In attendance: Orosia Asby, Dr Karen Desborough, Dr Carina Fraser, Emma Gore, Kim Mears, Catrin Morgan, Sarah Phillips (in part), Chris Shaw and Alison Tobin.

Apologies for absence were received from: Professor Oliver Ottmann, Professor Ian Weeks, Professor Roger Whitaker and Professor Gillian Bristow.

141 WELCOME AND INTRODUCTIONS

The Chair welcomed everyone to the meeting.

The Chair welcomed Dr Chris Whitman from ARCHI to his first meeting, as a new PSE representative.

142 DECLARATION OF INTERESTS

No declaration of interests were made during the meeting.

143 MINUTES

NOTED

That Professor Debbie Foster had raised queries with the Chair and Secretary to ORIEC regarding minutes 136.15-16. The queries have been resolved and responded to accordingly. The Secretary to ORIEC, Chris Shaw, will update the FAQ document that is available for SRECs on Microsoft Teams.

The Minutes (19/928) of the last meeting of the Committee were approved subject to minor amendments to minute items 136.15-16 to provide greater clarity.

144 MATTERS ARISING

Received and noted paper 20/130, 'Matters Arising' subject to the following additional matter:

NOTED

144.1 That the JOMEK annual report is due in the next few weeks;

144.2 That the Chair of ORIEC had sent an email to Head of Schools to reiterate that human participant research can continue and that participants travelling to attend a research project is accepted as a 'reasonable excuse' to travel;

- 144.3 That the above advice was based on discussions held with Welsh Government following the announcement of the firebreak. Such discussions confirmed that it did not matter where participants were travelling from (their locality) and that there were no geographical constraints to travel when the travel is essential for work;
- 144.4 That the University's existing risk management processes should identify anyone who is at a potential risk of transmitting COVID. Provided existing processes continue to be used and work effectively, there is no reason to change the current approach and advice.

145 **ANNUAL STATEMENT ON RESEARCH INTEGRITY**

Received and considered paper 20/131, 'Annual Statement on Research Integrity'.

NOTED

- 145.1 That the Annual Statement has already been received and noted by UEB;
- 145.2 That having looked at the approach taken across a random selection of Russell Group institutions, there appears to be a mixed approach on the reporting of student research misconduct cases within Annual Reports. Some Russell Group Universities only have one research misconduct procedure which applies to staff and students, therefore making reporting easier. Others have separate procedures for staff and students, like Cardiff University, and only some appear to specifically report on student cases;
- 145.3 That, in preparing the Annual Statement, the University's Research Integrity and Governance Officer, Emma Gore, had liaised with REGIS to ascertain whether assurances on student research misconduct procedures and case numbers could be reported. Following such discussions, it was determined that the University is not able to provide the relevant assurances and report on student case numbers at this time and that REGIS needs to review the University's approach to student research misconduct against the requirements of the Concordat to Support Research Integrity and UKRI policy in this area. REGIS will work towards providing the relevant information on student research misconduct in a future Annual Statement;
- 145.4 That the University needs to capture, and be able to report on, student 'research misconduct' cases specifically (as opposed to misconduct not relating to research activity, such as examination/assessment misconduct);
- 145.5 That UKRIO is due to publish a new version of its model research misconduct procedures for its member institutions. It is hoped that the model procedures will add more clarity as to what is expected of Universities;
- 145.6 That research misconduct allegations against PGR students are currently handled in accordance with the relevant student procedures, and not in accordance with the University's Academic Research Misconduct Procedure.

RESOLVED

- 145.7 That that Annual Statement be endorsed by ORIEC and approved for submission to Governance Committee, Senate, Audit and Risk Committee and Council;
- 145.8 That the approach taken across the Russell Group to investigating allegations of research misconduct against students be explored further, specifically whether one institutional procedure or separate procedures for staff and students is favoured across the Group;
- 145.9 That the Chair of ORIEC be available at Senate to support and answer questions on the Annual Statement.

146 RESEARCH ETHICS PROCEDURE

Received and considered paper 20/132, 'Research Ethics Procedures'.

NOTED

- 146.1 That Appendix 1 of the paper contains several matters arising for the Committee to note, including a reminder that, in August 2020, the Committee approved non-substantial and substantial amendment categorisations electronically;
- 146.2 That RIGE is awaiting two Annual Reports from SRECs. JOMEC has been chased and the Annual Report from MUSIC is imminent (awaiting Head of School signature);
- 146.3 That notwithstanding the one-year extension granted to Schools to implement the new SREC Procedures and templates, some Schools have started to implement the new procedures. Other Schools have retained their old procedures, and some have introduced step changes to get closer to full implementation;
- 146.4 That Appendix 2 of the paper provides some detail on Schools that have taken a partial approach to implementation at this stage;
- 146.5 That some Schools continue to raise concerns about the practical challenges surrounding the review of large numbers of student projects, particularly the additional hours and resource required to support implementation of the new ethics procedures. The paper contains an example/case study from GEOPL. This is an issue for SOCSI and CARBS. Schools are requesting ORIEC to provide practical solutions to the challenges faced by Schools with large numbers of student projects;
- 146.6 That three potential solutions were presented to ORIEC for consideration, namely:
- a) module wide ethical approval;

- b) different proportionate review criteria for UG/PGT projects for Schools with high volumes of projects;
- c) for student projects suitable for Proportionate Review, having 2 people review the ethics application form, but only one person (most likely the supervisor) review the supporting documents;

- 146.7 That the Committee has previously considered a proposal from GEOPL to use different review criteria and/or a different review process for UG/PGT projects and that the Committee had rejected that proposal and made it clear that the same review criteria was needed for staff and student projects;
- 146.8 That the supporting documents submitted as part of an application for ethical review are often key in enabling an ethics committee to understand what the project is and whether participants are being treated ethically, as such they must be reviewed by two people (although see 146.9 below in relation to the research protocol/proposal specifically);
- 146.9 That SRECs could reduce the time taken to review supporting documents by making templates and/or examples available to researchers; similarly, it was noted that in some Schools template protocols or 'master protocols' are utilised meaning that SRECs are often already familiar with much of the protocol content before the ethical review application is received (meaning a review of every detail is often not necessary);
- 146.10 That Schools with high volumes of student Human Research projects need to think more broadly about changing the way student research is undertaken if workload/capacity remains an issue, rather than seeking to deviate from the University's ethics procedures. Changes in practice and behaviour may be required;
- 146.11 That Schools with high volumes of student Human Research projects may want to consider the value of secondary data analysis/research and how endorsing such a model (at least for some students) may reduce the number of projects requiring ethical review; similarly, Schools could utilise template or example supporting documents;
- 146.12 That one SREC Chair had voiced concern about the potential pressure placed on SREC members, and a potential power imbalance, in cases where there is one SREC reviewer and one non-SREC reviewer (who may be a senior academic); concern was raised about SREC members being pressured (or feeling pressured) to take a particular decision;
- 146.13 That CARBS has established a task and finish group to assess how it can implement the new Ethics Procedures and templates and what resources are required (both in terms of Academic Staff time and Professional Services support). The group is meeting on 09 November initially and will meet four times, before approaching the College of AHSS with its findings. The group will be looking at setting up a process to manage the high numbers of student ethics applications.

- 146.14 That CARBS would welcome input/representation from RIGE to help deliver messages about the new Ethics Procedures;
- 146.15 That some tasks, such as reviewing ethical review applications, can only be undertaken by Academic Staff and cannot be delegated to Professional Services and that this does have implications for resources and workloads;
- 146.16 That the competence and knowledge of supervisors in research ethics remains an issue in some Schools and the University needs to assess its approach to research ethics training and think about whether a specific 'Research Ethics' training programme is required prior to research being conducted;
- 146.17 That, as requested by ORIEC at its previous meeting, the paper and Appendix 3 provides further information about Human Research Projects that were undertaken without ethical approval in place. All cases involved student projects (PGT or UG) and all were referred to the SREC (although the exact referral routes varied);
- 146.18 That the further information provided by Schools reporting cases of Human Research proceeding without ethical review indicate that different approaches are taken to dealing with such cases. The paper therefore recommends that all cases of Human Research projects proceeding without a favourable ethical opinion be dealt with under the University's Academic Research Misconduct Procedures (for staff cases) and Academic regulations/Academic Misconduct Procedures (for students);
- 146.19 That the information provided by Schools at Appendix 3 of the paper indicates that some students have been given incorrect advice or have not received the right support. The recommendation in 146.18 above would ensure a uniform approach to dealing with such cases;
- 146.20 That queries have arisen in relation to what 'where relevant' means in terms of applicants providing the listed 'Supporting Documents' with their application for ethical review; SRECs have queried whether a research protocol/proposal is required in all cases as these are not routinely prepared in some Schools for UG and PGT projects and/or the application form for ethical review effectively comprises the protocol;
- 146.21 That whilst the Committee considered a research protocol/proposal to be a key document, on reflection it was unclear what additional information would be contained in a research protocol/proposal that is not already contained in the application form;
- 146.22 That, in respect of the request from some AHSS Schools to remove the Human Tissue Questions from the template Application Form, this would pose a significant risk to the University and should not be supported, particularly as responding to the questions for those not conducting human tissue research is quick and unproblematic. It is fundamental that the University knows where human tissue research is taking place (across the University) and the questions must remain in the form.

RESOLVED

- 146.23 That partial implementation of the new procedures and steps taken by Schools during this Academic Year be reviewed as part of the next annual reporting process (February/March 2021) and considered by ORIEC at its May 2021 meeting;
- 146.24 That in respect of potential solutions for Schools dealing with large numbers of student projects:
- Option a is viable and broadly supported by the Committee, albeit further consideration of the finer details is required (including whether 'module-wide' is the correct terminology, whether this process could in fact apply to a number of different 'groups' of projects following the same ethical framework or 'master protocol' and whether further assurances/action is required to ensure an appropriate ethical education for students and the applicant (supervisors/module leaders in most cases));
 - Option b is rejected and not considered viable by the Committee. The Committee reiterated that it cannot support different full/proportionate review criteria for staff and students and that the criteria must be based on the 'activity' rather than the 'researcher';
 - Option c is also rejected. The Committee noted that SRECs could reduce the time taken to review supporting documents by having template or example documents available;
- 146.25 That RIGE work with SRECs and update the FAQ document to provide further clarity on what is meant by 'second reviewer' and make it clear that the SREC (and its members) are the ultimate decision maker on matters of research ethics;
- 146.26 That the recommendations contained at Section 5.3 of the paper (Human Research projects commencing prior to receipt of a favourable ethical opinion) be approved and communicated to Schools;
- 146.27 That the Human Tissue questions remain in the template Application Form for all Schools, but that consideration be given to whether the questions can be consolidated as part of the next review cycle;
- 146.28 That the Chair and Secretary of ORIEC consider the extent to which AHSS Schools can be offered any further support in implementing the revised ethics system and considering approaches to dealing with high volumes of student Human Research projects;
- 146.29 That consideration be given to whether the University's Research Integrity Training should be expanded to include further content on research ethics, or whether a separate training programme/module on research ethics is required for SREC applicants (and supervisors specifically);
- 146.30 That the 'Supporting Documents' section of the Application Form for Ethical Review should remain unchanged for the time being, but that this (and

particularly whether a protocol/proposal is a mandatory document) be revisited following feedback from SRECs as part of the next annual reporting cycle;

- 146.31 That the Committee take a detailed look at the Application Form for Ethical Review more broadly, following feedback from SRECs as part of the next annual reporting cycle.

147 **RECORDS/DATA RETENTION POLICY**

Received and considered paper 20/133, 'Records/Data Retention Policy.

NOTED

- 147.1 That the paper proposes that the University's retention periods for research records and data be changed to make them clearer and easier to implement. The proposal seeks to accommodate the different approaches and disciplines, set up minimum standards and give additional clarification to researchers. Those who want, or need, to keep records or data for longer can do so, but the proposal sets out the University's requirements as a minimum basis.

RESOLVED

- 147.2 That the final paragraph of Section 6 of the paper be amended to replace the word "should" with "must";
- 147.3 That the paper be submitted to UEB for review and that the Chair of ORIEC sponsor the paper at UEB.

148 **PUBLICLY AVAILABLE DATA TASK & FINISH GROUP**

Received and considered paper 20/134, 'Publicly Available Data Task & Finish Group'.

NOTED

- 148.1 That the Group's recommendations for ORIEC to consider and approve are at Paragraph 4.1 of the paper. These recommendations comprise a framework for the ethical review of projects that only use publicly available or secondary data and recommendations on how to incorporate the framework into current University processes;
- 148.2 That it is important for the University to be clear on what ethical review is required for data-only projects;
- 148.3 That in respect of the proposed new exemption wording at Paragraph 4.2 of the paper, the 'conditions' referred to are set out in the framework; researchers would need to refer to the framework to see the conditions and ascertain whether ethical review is required.

RESOLVED

148.4 That ORIEC approve the recommendations contained at Section 4 of the paper.

149 RESEARCH INTEGRITY ACTIVITY UPDATE

Received and considered paper 20/135, 'Research Integrity Activity Update'.

NOTED

- 149.1 That a request has been received from MLANG to exempt some of its staff from the mandatory requirement to complete the University's Research Integrity Online Training Programme (RI Training). MLANG wishes to exempt its hourly paid language tutors and those teaching on the 'Languages for All' programme as these staff have no involvement in research or research supervision. The University's Research Integrity and Governance Officer noted that CARBS may wish to make a similar exemption request in respect of its 'UT' staff who conduct no research and fall under a T&S pathway;
- 149.2 That the Committee would be uncomfortable supporting an exemption request from an individual School; the Committee would prefer to keep the mandatory groups under review across the whole University so that the requirement can be implemented consistently;
- 149.3 That it is important to ensure that any staff responsible for supervising student research projects are captured by the mandatory completion group; even staff who do not formally supervise research projects will still come into contact and teach students who are required to conduct research so ensuring they have appropriate knowledge is still preferable;
- 149.4 That WELSH is not able to mandate the completion of the RI Training locally if it is not available in the Welsh Language. WELSH has specifically referred to its promise to students to provide 100% education in the Welsh language.
- 149.5 That advice has been sought from Compliance and Risk in respect of the University's Welsh Language Standards, and they have advised that the RI Training does not fall within the strict requirements for translation but that consideration should be given to whether this would still be best practice;
- 149.6 That, given the advice from Compliance and Risk, and the significant resource implications for the Translation Team and RIGE in translating both the staff and student versions of the training, RIGE proposes that the student version of the training is translated and that staff who wish to complete the training in the Welsh language be referred to the student version (given that the content is largely the same). RIGE believes this is an appropriate compromise given work volumes and resource;
- 149.7 That the Research Culture Working Group (RCWG) has requested a summary of the work that RIGE has completed around reviewing the

University's performance on Research Integrity against the Concordat to Support Research Integrity. A summary paper has been prepared by the University's Research Integrity and Governance Officer. ORIEC is asked to approve the paper and confirm that it can be shared with Members of the RCWG;

- 149.8 That close collaboration between ORIEC and the RCWG is important and that sharing this information will help the RCWG to think about the implementation of some of the ideas it is developing;
- 149.9 That student completion rates for the RI Training are positive, however, academic staff completion rates continue to be low. RIGE has been provided with points of contact for the majority of Schools (six Schools have yet to identify a point of contact; RIGE is chasing). RIGE has provided all points of contact with updated completion reports during October so that local action can be taken to help improve completion rates;
- 149.10 That ensuring completion of the RI Training by REF eligible staff must be the main priority at the current time.

RESOLVED

- 149.11 That MLANG's exemption request be rejected, but that the Committee considers, at a future date if required, whether the current mandatory groups need to be amended across the whole University;
- 149.12 That the Committee does not support the proposal that staff be permitted to complete the student version of the RI Training. The Committee requires that both the staff and student version of the RI Training be translated;
- 149.13 That ORIEC approves the paper to the RCWG and agrees that it can be shared with Members of the RCWG;
- 149.14 That the Chair of ORIEC discusses RI Training completion with the College PVCs to ascertain what further action can be taken to improve Academic Staff completion rates;
- 149.15 That RIGE provide a breakdown of completion rates in respect of REF eligible staff, working with the University's REF Manager/Team.

150 ASSURANCE SERVICES ACTIVITY UPDATE

Received and considered paper 20/136, 'Assurance Services Activity Update'.

NOTED

- 150.1 That Compliance and Risk would like to see the new model policy from UKRIO before finalising the update to the University's policy. Compliance and Risk is hoping to start the consultation process shortly.

151 REPORTS RECEIVED BY THE COMMITTEE

Received and noted papers 20/137 'OROG report to ORIEC', 20/138 'DWG report to ORIEC', 20/139 'BSC Chair's report to ORIEC', 20/140 'HTSC report to ORIEC' and 20/141 CTIMPGG report to ORIEC'.

NOTED

Open Research Operational Group (OROG)

- 151.1 That OROG hopes to get the Open Research Integrity Leads in place during 2021.

DORA Working Group (DWG)

- 151.2 That a Responsible Research Assessment Healthcheck has been developed for Schools to raise awareness of DORA and responsible research assessments, practices, processes and policies at the University. It will be asking for Schools for feedback on how they would incorporate DORA locally;
- 151.3 That a copy of the Healthcheck will be provided to ORIEC for approval once it has been approved by the DWG.

Biological Standards Committee (BSC)

- 151.4 That a new committee chair was appointed at the last meeting and that Professor Ian Weeks is the new establishment licence holder. There is a new home office inspector and the department of the government that looks after animals has a new name.

Human Tissue Standards Committee (HTSC)

- 151.5 That Professor Ian Weeks has been confirmed as the corporate licence holder contact for the University by the Human Tissue Authority.

Clinical Trials of Investigational Medicinal Products Governance Group (CTIMPGG)

151. Nothing additional to note.

152 ANY OTHER BUSINESS

NOTED

- 152.1 That an external researcher has requested permission to undertake a project that involves interviewing multiple staff and students from different Schools and departments. Ethical review has been undertaken by the University of Lancaster;

- 152.2 That the University's ethics policy does not address this particular scenario. The project does not involve one specific department or School, therefore it is not appropriate for the project to be referred to a specific SREC;
- 152.3 That a query has arisen from BIOSI, but it is not clear whether it is an ethics question. The query relates to publication processes and sharing of data with the funding organisation (Fund for Replacement of Animals in Medical Experiments).

RESOLVED

- 152.4 That the Chair and Secretary of ORIEC consider the process to be followed in respect of the request from an external researcher to conduct research with staff and students from multiple Schools;
- 152.5 That the Committee is happy to consider the proposal remotely, if required;
- 152.6 That the Secretary of ORIEC consider the BIOSI query and discuss with BIOSI.

Date of next meeting 9th February 2021, at 10.00am.