University of BRISTOL

Research Committee

MEETING DATE	16/05/2024
REPORT TITLE	Restructuring Research Ethics
CLASSIFICATION	Open
REPORT AUTHOR	**Ingeborg Hers, Deputy Chair, University Ethics of Research Committee (UERC)** **Liam McKervey, Research Ethics and Integrity Manager** **Adam Taylor, Head of Research Governance**
SPONSORED BY	Matthew Brown, Chair, University Research Ethics Committee
PURPOSE	For Approval

Proposal/Recommendation. The Research Committee is asked to: Approve the proposals outlined in the paper and to note the appendices.

Summary of Paper History and Onward Consideration/Decision Making   Yes

The paper is the result of discussion at University Ethics of Research Committee, the formation of a Task & Finish Group, and input from Academic Leadership Board and a Critical Friends group of former UERC members and the APVC for Research Culture.

Does this report need to go to another body or Committee?   Yes

Executive Summary

We propose to change the way we facilitate the ethical review of research at the University of Bristol, moving from a multi-siloed faculty and school model - which will no longer be feasible under the new faculty structure and which has tended to result in high workloads and delays, - to a single cross-institution system for ethical review with applications divided into 4 workstreams according to the type of proposal rather than its institutional home.
This paper sets out how this will work, and how it will facilitate improvements in the development of cross-institutional guidelines and sharing best practice, and addressing high workload and delays.

Strategic Outcomes

This proposal will enable the University to increase the scale of high-quality, high-impact research to address local, national and global challenges. It is conceived to nurture supportive and inclusive research cultures.

Key University Risks Current KURR Risks **Yes**

UERC examined the structures for considering Research Ethics in the light of the proposed University restructure. It should be considered as part of 0A Change – we have reassessed our priorities and proposed new systems for delivering our goals and 3A Staff work-related stress.

Equality Impact Assessment (EIA) undertaken **Yes**

The proposal aims to more effectively monitor processes across the University. EDI considerations will be taken into account when making new appointments to Research Ethics review groups and committees.

Appendices/Reading Material Attached **Yes**

Appendix 1 – Updated UERC Terms of Reference v3.0
Appendix 2 – Updated Ethics of Research Policy and Procedure v9.3

1. **Summary**
   1.1. We propose to change the way we facilitate the ethical review of research at the University of Bristol, moving from a multi-siloed faculty and school model which can be characterized by high workloads and delays, to a single cross-institution system for ethical review with applications divided into 4 workstreams according to the type of proposal rather than its institutional home.

2. **The problem**
   2.1. Research Ethics should enable excellent research rather than being a bureaucratic barrier to it. There are three main concerns with the current system:

   2.1.1. Too much bureaucracy with complex forms going back and forth
      2.1.2. Too much workload for committee members
      2.1.3. Too much detailed critique of individual projects with not enough training or best practice guidelines to support researchers.

   2.2. Research Ethics has been based around Faculty review at Bristol, and University Ethics of Research Committee has overseen this since 2003/04.
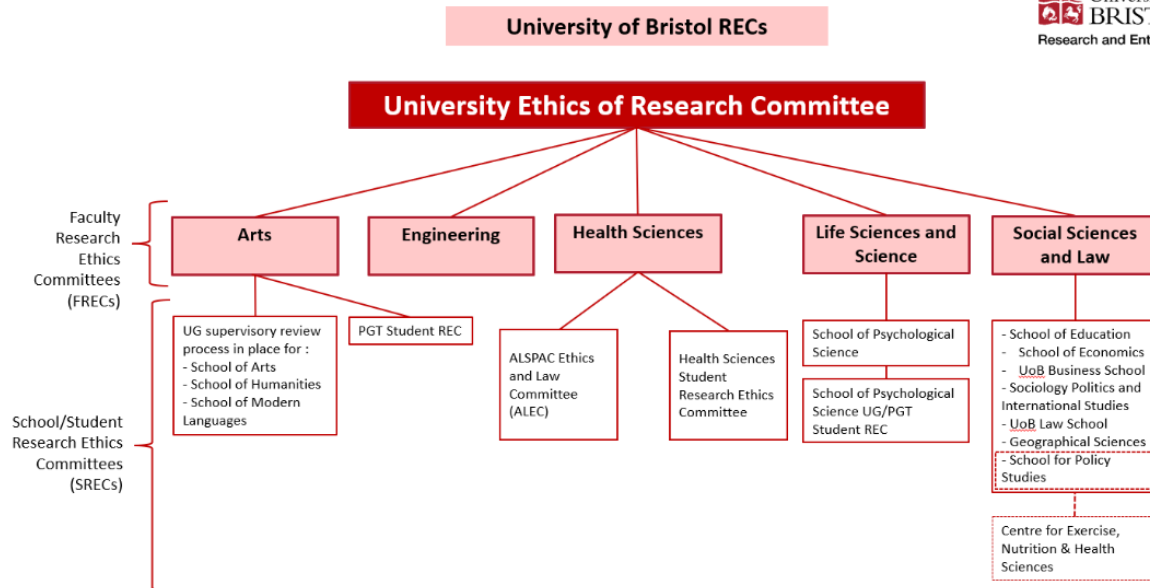   2.3. The massive expansion of applications for formal research ethics approval has meant that this system has not been fit for purpose for some time.

Number of ethics applications UOB
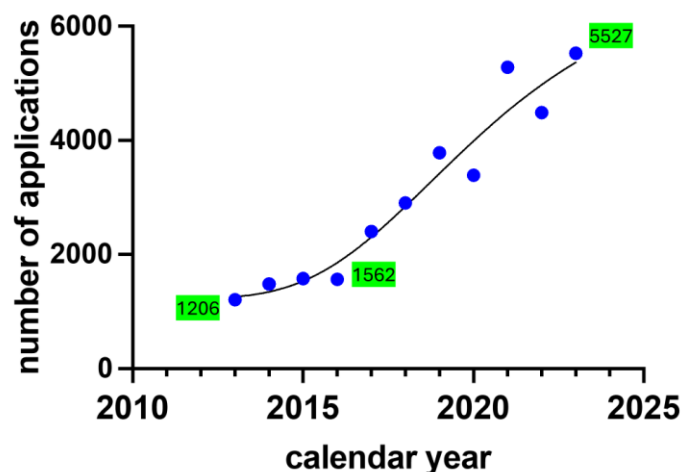
   2.4.

   2.5. To deal with the increase in the number of applications for the review, Faculty Research Officers have expanded the membership of their committees (there are currently 179 committee members across UoB) and set up new School Research Ethics Committees, and new committees delegated to look solely at PGT or undergraduate applications. 18 separate Research Ethics committees currently report annually to UERC. The efforts of Professional Services staff in supporting these committees and their paperwork have been heroic. Only the dedication, commitment and hard work of colleagues in this area has prevented these pressures from falling into total crisis and collapse.

University of Bristol RECs — University Ethics of Research Committee organisational chart. Faculty Research Ethics Committees (FRECs): Arts, Engineering, Health Sciences, Life Sciences and Science, Social Sciences and Law. School/Student Research Ethics Committees (SRECs): UG supervisory review process in place for: - School of Arts, - School of Humanities, - School of Modern Languages; PGT Student REC; ALSPAC Ethics and Law Committee (ALEC); Health Sciences Student Research Ethics Committee; School of Psychological Science; School of Psychological Science UG/PGT Student REC; - School of Education, - School of Economics, - UoB Business School, - Sociology Politics and International Studies, - UoB Law School, - Geographical Sciences, - School for Policy Studies; Centre for Exercise, Nutrition & Health Sciences.

3. The solution

3.1. Our guiding principles have been to encourage and facilitate best practice in the ethical conduct of research, to ensure that Research Ethics policies and guidelines are implemented effectively and with consistency, and to comply with UKRI guidance on good practice in Research Ethics governance. Simplifying our committees into one cross-institutional arrangement for research ethics will bring a range of benefits:

3.1.1. Share best practice across the University in a practical sense through everyday working together in a horizontal fashion, rather than the current vertical silos. This will enable the production of cross-institutional guidelines on difficult areas.

3.1.2. Reduce delays by having a series of reviewing groups that will better manage peaks in applications.

3.1.3. Better fulfil the UKRI guidelines on research ethics review, which recommend avoiding tightly-focused review within individual disciplines.

3.1.4. Remove single points of failure from our processes.

3.1.5. Reduce the amount of workload hours dedicated to reviews in the medium-term, as a result of better training and more effective guidelines earlier in the process.

3.2. **What will the new system look like?**
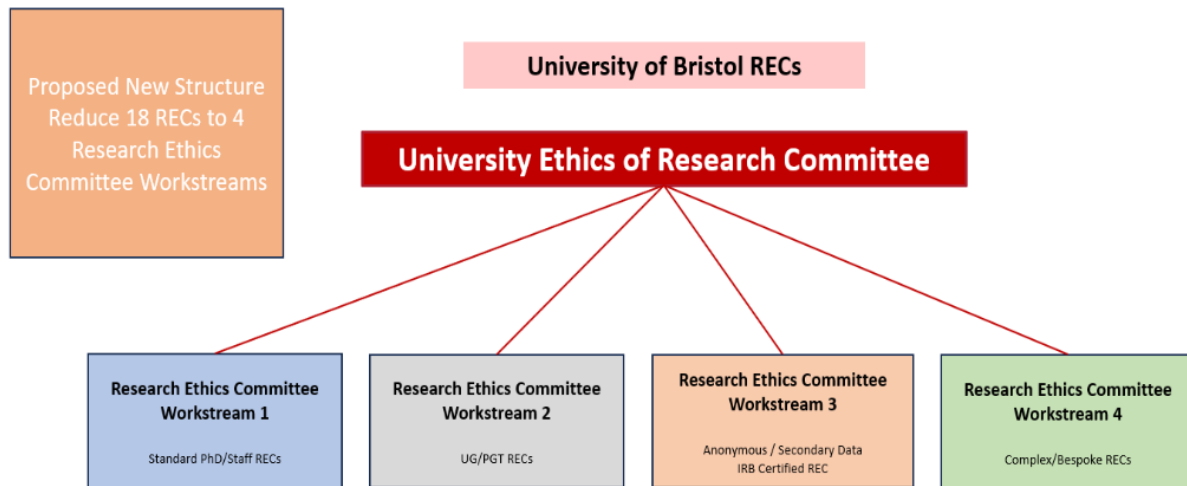
The proposed REC restructure will include committee membership from a broad membership from across the university.

3.3. How will it work?

3.3.1. All applications for research ethics approval will be submitted via the existing Online Research Ethics Management System (OREMS)

3.3.2. All applications will be triaged by professional services specialists, first into the appropriate workstream, and then into the type of attention it requires for approval.

3.3.3. Each application will be filtered into 1 of 4 Research Ethics Committee (REC) Workstreams for review.

3.3.3.1. REC Workstream 1: PGR and Staff Applications

3.3.3.2. REC Workstream 2: Undergraduate and PGT Applications

3.3.3.3. REC Workstream 3: Secondary-Use Research Data

3.3.3.4. REC Workstream 4: Bespoke / Complex Projects

3.3.4. Each of the 4 Workstreams will report to UERC via their Chairs.

3.4. Workstream 1: PGR and Staff Applications

3.4.1. Workstream 1 will review most (c.95%) applications for Research Ethics Approval from Staff and PGRs (the exceptions will go into Workstreams 3 and 4).

3.4.2. Workstream 1 will consist of 10 Review Groups, each with a chair and 5 members including an Independent Member. These members will be drawn in the first instance from existing Faculty Research Ethics Committees, and will have a range of disciplinary expertise. Each of the 3 faculties will be represented on each Review Group. In the first instance, each Review Group would meet every six weeks (8 times a year), meaning that Workstream 1 will have a total of 80 meetings per year, in line with existing practice. UERC will keep the number of meetings required each year under review, and will modify this in line with demand.

3.4.3. Applications will be assessed by the Research Governance Teams as requiring; Chairs Review, Virtual Review or Discussion Review:

3.4.4. CHAIR'S REVIEW

3.4.4.1. Proposals which do not require Virtual or Discussion Review will be assigned to the chair of a Review Group, or their delegated representative - to confirm that further review is not required. 10% of these proposals, chosen at random, will be cross-checked by one of the other Review Groups - in order to quality control the process. This cross-checking will not impact or delay confirmation for the studies involved.

3.4.4.2. The Chair or their delegated representative may determine that a proposed study is not appropriate for this process and instead refer it for further review.

3.4.5. VIRTUAL REVIEW
3.4.5.1. Each Virtual Review application will be assigned to three specific Review Group members (one primary, two secondary reviewers) through the OREMS system, who will leave comments on OREMS in advance of the meeting. Applications can be signed off on OREMS (virtual review, quorate 3 members) and/or following discussion at the REC meeting. We expect a combination of virtual review with discussion at the scheduled meetings may be a good compromise.

3.4.6. DISCUSSION REVIEW
3.4.6.1. Discussion review applications will be made available to all Review Group members in advance of the next scheduled meeting, via OREMs, and will be discussed in full at that meeting.
3.4.6.2. We expect WS1 to review around 700 applications per year.
3.4.6.3. We recommend that members of the Review Groups are allocated 50 hours per year in their Workload Credits Allocations, and that the chairs of each of the 10 groups are allocated 100 hours. Our recommendation for workload credits will remain under continuous review and monitored by the University Ethics of Research Committee

Research Ethics Workstream 1
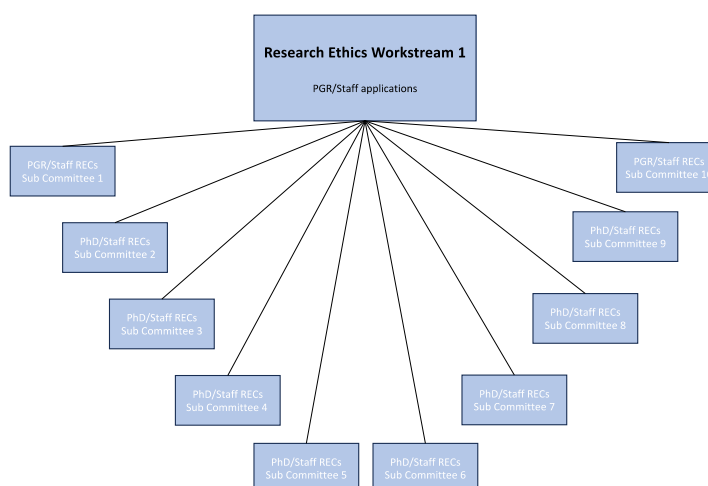
3.4.6.4.

3.5. **Workstream 2: Undergraduate and Postgraduate Taught Applications:**

3.5.1. WS2 will coordinate the review of all applications for research Ethics approval from Undergraduates and Postgraduate Taught students. In 2023 there were over 4,500 applications to be considered, and we expect this number to continue to grow.

3.5.2. Because of the distinct educational function of WS2, Schools will continue to organize the review of their students' applications, according to existing procedures from this suite of current ways of working:

3.5.2.1. School Undergraduate and Post Graduate Taught Research Ethics Committees as is currently done in the Faculty of Health Sciences and the School of Psychological Science

3.5.2.2. Supervisor Sign-Off for Dissertations as is currently done in the School of Arts, and the School of Humanities

3.5.2.3. Supervisor and Dissertation Convenor approvals as is currently done in the School for Policy Studies

3.5.2.4. Blanket Unit Approvals as is currently done in the Faculty of Engineering

3.5.3. The innovation is that Schools' processes will now be monitored and reviewed by the University-wide WS2 rather than by Faculties which then reported to UERC. Any WS2 applications which need more extended consideration before approval will be escalated to one of 2 WS2 Review Groups.

3.5.4. Each of the WS2 Review Groups will have a chair and 5 members including an Independent Member. Each of the 3 faculties will be represented on both of the review groups.

3.5.5. We recommend that members of the WS2 Review Groups are allocated 20 hours per year in their Workload Credits Allocations, and that the chairs of each of the 2 groups are allocated 50 hours.

3.5.6. Annually, WS2 will sample 10% of each Schools' approvals, and report to UERC.

3.5.7. WS2 will work with Faculty Research Ethics Officers and Faculty Education Directors to coordinate best practice in education and training for UG and PGT students and their supervisors, for example handbooks and asynchronous training sessions. There is a lot of evidence that the quality of UG applications is improved where handbooks and training have been introduced and improved. This is a crucial innovation.

3.6.   Workstream 3: Secondary-Use Research Data

3.6.1. WS3 is a bespoke research data workstream. It will consist of two Review Groups:

3.6.1.2. ALSPAC Law and Ethics Committee (ALEC), which remains Institutional Review Board (IRB) Certified and so can review research involving access to US datasets / NIH funded research and is constituted with Data Research specialists.

3.6.1.3. A new WS3 Review Group will be established and have IRB certification. This committee will have data science experience and not be considered as a bio-medical panel. Training will be given regarding ethical issues at an infrastructure level, and which are relevant at a project level. Its chair will be tasked with developing Standard Operating Procedures to capture consistency, expectations and outcome. The volume of IRB applications

will be monitored to determine if it is viable to maintain two IRB certified panels in the medium-term.

3.7. **Workstream 4**: **Bespoke / Complex Projects**

3.7.1. WS4 will provide the flexibility to deal with particularly complex or pioneering projects, drawing members from workstreams 1-3 when deemed appropriate, plus experts with experience in the field where necessary.

3.7.2. Fields where we would expect to use WS4 in the near future include impact/public engagement work, Global South partnerships, and Artificial Intelligence and complex technologies.

3.7.3. Bespoke panels will be created through the OREMS triage system rather than populated in advance. Research Governance maintains a register of experts who can be called on. This enables a dynamic response to emerging (unforeseen) needs. Chairs of WS1, WS2 and WS3 will be able to send applications back via the triage panel for consideration by WS4.

3.7.4. The WS4 chair will appoint the chairs and members of any bespoke panels as and when required, using the Research Governance register of experts.

4. **Reporting to UERC**

4.1. University Ethics of Research Committee has reviewed and refreshed its Terms of Reference, which are appended to this report.

4.2. The chairs of the 4 workstreams will meet quarterly with the Research Ethics and Integrity Manager and will report annually to UERC.

4.3. In addition to its existing chair, Independent Members, chair of AWERB and PGR representative, and professional services members, in the new structure UERC would have two representatives from each of the new faculties, ie:

4.3.1. Arts, Law and Social Sciences: 2 members of UERC

4.3.2. Health and Life Sciences: 2 members of UERC

4.3.3. Science and Engineering: 2 members of UERC

4.4. 4.4. The existing 6 Faculty representatives would roll over into these new roles on 1 August 2024.

4.5. When their terms end, it would remain the responsibility of Deans (currently known as PVC Faculties) to recruit and appoint their replacements, confirmed by Senate.

4.6. To maintain the existing system of UERC being independent from the reviewing processes it oversees, the faculty representatives on UERC would not sit on review groups in either Workstream 1, 2 or 3. They may, however, be invited to sit on the occasional bespoke panels in Workstream 4.

4.7. We recommend that membership of UERC should be allocated 50 hours of workload.

5. **Training and Sharing Best Practice**

5.1. The restructuring into Workstreams as outlined above will provide the firm foundations that are needed for system-wide change. On its own the administrative change will not be enough. The restructure will enable the sharing and implementation of best practice across the institution.

5.2. Faculty Research Ethics Officers will now be freed from chairing committees, and will focus on training and sharing best practice.

5.3. Each of the 3 faculties will have a <u>Faculty Research Ethics Officer</u> who will be in charge of training in research ethics, being the point of contact for the ethical review process and for sharing best practice within their faculty. They sit on or report to <u>Faculty Research Committee.</u>

5.4. Each School should have a <u>School Research Ethics Officer</u> with the same responsibilities at their level. They can have the option to sit on Workstream Review Groups, or to be co-opted as an additional reviewer if necessary.

Research Ethics Training and Education

University Ethics of Research Committee

Faculty Research Ethics Officers (FREOs)
Undertake awareness raising, provide advice and guidance and can convene to meet to discuss appeals / breaches / and escalations

School Research Ethics Officers (SREOs)
Undertake awareness raising, provide advice and guidance and can have the option to sit on REC Workstream Review Groups, or to be co-opted as an additional reviewer if necessary.

Freed from chairing committees, and undertaking research ethics reviews, F/SREOs will focus on training, developing guidance and sharing best practice developed within their schools with other REC Workstreams, Review Groups and Researchers.

5.5.

5.6. The Faculty Research Ethics Officer will chair a meeting of School Research Ethics Officers in their faculty 4 times a year, to discuss issues relating to approvals, training and horizon-scanning.

5.7. The 3 Faculty Research Ethics Officers will <u>report to UERC</u> every year on the data relating to their Faculty provided from OREMS by the Research Governance team.

5.8. We recommend that the Faculty Research Ethics Officers are allocated 100 hours of their workload per year, and the School Research Ethics Officers 50 hours.

5.9. UERC will have as its priority in 2024/25 the reboot of our training programmes and the development of clear and accessible guidelines to support the work of the Faculty Research Ethics Officers. This starts with the 26 June 2024 Bristol Research Ethics Workshop, at which we are recording asynchronous training materials to be made available in September 2024.

6.   Implementation

6.1. We will work on developing training materials and guidelines, and on restructuring the OREMS system over summer 2024.

6.2. We will implement the new system in stages during 2024/25. It will be fully functioning by 1 September 2025.

Appendix 1:

University Ethics of Research Committee Terms of Reference

Version 1. Significant Amendments throughout suggested by Matthew Brown, 18.4.24, circulated to UERC members. A clean revised version will be produced on 24.4.24.

Version 2. Amendments made throughout suggested by Matthew Brown, Adam Taylor and Liam McKervey produced on 30/04/24, MB_AT_LMK

Version 3. Clean version produced 30.04.24

RC/22-23/038 UNIVERSITY ETHICS OF RESEARCH COMMITTEE

TERMS OF REFERENCE

1. Authority

1.1 The Ethics of Research Committee is a sub-committee of the University Research Committee, which is a committee of Senate. Subject to the provisions made in the Charter, Statutes, Ordinances, and Regulations, the University Ethics of Research Committee shall operate within the duties and authorities as stipulated by the University Research Committee in these Terms of Reference.

1.2 The University Ethics of Research Committee is authorised by Senate to investigate any activity within its remit as set out in these terms of reference. In order to do so, the Committee is authorised to request relevant information and question any employee of the University as and when required.

2. Purpose of the Committee

2.1 University Ethics of Research Committee exists to promote a culture of dialogue, openness and collaboration in Research Ethics that will make the University of Bristol a centre of excellence in the review and oversight of ethics in research. The Committee is responsible for oversight of research ethics across the University, and its purpose is to encourage and facilitate best practice. It reports to Senate via the University Research Committee. It serves to adjudicate appeals in relation to decisions made by all other Research Ethics Committees. UERC's oversight responsibilities are both strategic and operational.

3. Membership

3.1 The University Ethics of Research Committee will normally comprise up to fifteen members.

3.2 The membership will be as follows:

• The Chair will be a University of Bristol member of staff with experience of human participant research. The position of Chair will confer a seat on the University Research Committee and on Senate;

• Two members from each of the Faculties of Arts, Social Sciences and Law, Science & Engineering, and Health and Life Sciences appointed by their Dean and ratified by the University Research Committee (URC)

• The Chair of the Animal Welfare and Ethical Review Body (AWERB) (or a delegated member);

• The Head of Research Governance;

• The Research Ethics and Integrity Manager;

• The Registrar and University Secretary (or delegate);

• Co-opted members as agreed by Senate, including an academic member who sits upon the Board of Trustees;

• At least two Independent Members, in line with UKRI best practice on Research Ethics;

• One of the Elected Postgraduate Research or Taught Faculty Representatives as agreed upon amongst themselves.

3.3 Other staff will be invited to join the meeting for their relevant items.

3.4 The quorum is five, to include the Chair or Deputy Chair, at least two faculty members, and an Independent Member. Attendance will normally be in-person. Hybrid meetings can enable online participation where necessary.

3.5. UERC will meet five times a year. Meetings will be up to three hours in length. The third meeting of the year will be primarily dedicated to discussion of reports from workstreams, research ethics committees and Faculty Research Ethics Officers. The date for receipt of these reports is 28 February each year. The final meeting of the year, in June, will be linked to an event primarily dedicated to sharing best practice beyond the committee: the Bristol Research Ethics Workshop.

4 Specific Duties

4.1 The University Ethics of Research Committee's strategic duties are:

4.1.1 To identify emerging ethical/integrity issues.

4.1.2 To identify and encourage adoption of best practice in research ethics across the University.

4.1.3 To confirm the University's compliance with the Concordat to Support Research Integrity.

4.1.4 Maintain and implement the University's Ethics of Research Policy and Procedure;

4.2 UERC's operational duties are:

4.2.1 To maintain procedures for Research Ethics approvals across the University.

4.2.2. To embed best practice and effective processes in Research Ethics Committees across the University.

4.2.3 To audit and report on compliance across all Research Ethics Committees

4.2.4 To report on non-compliance and make recommendations to learn lessons, through effective and reciprocal engagement with the University Research Committee;

4.2.5 Receive, discuss, and act upon an annual report before 28 February each year from:

• the Human Tissue Working Group;

• the Head of Research Governance on engagement with NHS Research Ethics Committees;

• the Animal Welfare and Ethical Review Body;

• all of the Faculty Research Ethics Officers, Workstreams, Review Groups and Committees and sub-subcommittees.

4.3 Other duties

4.3.1 The Committee will consider research ethics and integrity issues referred to it by Workstreams, School or Faculty Research Ethics Officers or Committees, or by any other person or body in the University, in accordance with the Ethics of Research Policy and Procedure. It will draw up, share and update guidelines of best practice. Examples of issues which the committee might consider are:

• ethical status of research involving human participants, their tissue and/or data;

• research ethics and integrity issues connected to advanced scientific research;

• research issues relating to the environment;

• due diligence in relation to donors to the University who are funding University research;

• appeals that cannot be resolved within other procedures.

4.3.2 Where the Committee is of the view that a current or proposed research activity or practice in the University is unethical or an ethics issue needs resolving, it will report this directly to the Vice-Chancellor and the Chair of the Board of Trustees for resolution.

4.3.3 It is within the Committee's remit, and the Committee's responsibility, to consider any implications linked to equality, diversity and inclusion when conducting its business, making decisions and agreeing actions.

4.4.4 Representatives of UERC will routinely visit each of the Workstreams and Review Groups(and any Faculty or School Research Ethics Committees) to offer support and to gain feedback from committee members about their ethics review experiences.

5. Accountability and Reporting

5.1 University Ethics of Research Committee is a sub-committee of University Research Committee, the Chair of the Committee shall report formally to the University Research Committee on its proceedings after each meeting on all matters within its duties and responsibilities. The University Research Committee, in turn, will report formally to the University Executive Board and to Senate, and therefore to the Vice-Chancellor who chairs both of these bodies.

5.2. The Committee will provide an annual report to URC and to Senate on how it has discharged its duties during the previous academic year. UERC will explicitly request feedback from both URC and Senate as to how effectively it is perceived to be fulfilling its duties.

5.3. Exception Reporting. When it has concerns that University Research Committee is not taking due notice of UERC's recommendations, it will report this directly to the Vice-Chancellor.

5.4. Where authority has been delegated to the Committee by Senate or University Research Committee to perform a particular action or take a particular decision, that action or decision will be reported to the parent body as soon as is practical after the action/decision has been taken.

5.5. The Committee may make recommendations to its parent body on any matter within its remit, authority and responsibilities.

6. Effectiveness Monitoring and Compliance with Terms of Reference

6.1 To review committee effectiveness and efficiency annually including:

• its remit, authorities and powers as stipulated in its Terms of Reference;

• its membership, making sure that term-limits are observed and due planning is made to replace members completing their terms of services.

6.2. At the first meeting of each academic year UERC will identify up to three areas of priority. At its final meeting of each academic year, UERC will discuss how effectively it has developed these areas.

7. Secretarial support

7.1. Secretary to the Committee – a member of the Research Governance team, in DREI.

8. Resourcing

8.1. Resources necessary to the effective functioning of UERC (travel expenses for Independent Members, the development of materials relating to best practice, etc) will be provided by the Pro Vice Chancellor for Research and Innovation.

8.2. Training on how to navigate regulatory approval processes including obtaining a research ethics review is delivered by the Research Governance team based in DREI, and will be resourced accordingly.

8.3. Training in the ethical and appropriate conduct of research will be provided to staff and student researchers within their faculty.

Approval date: University Research Committee 18th May 2023 Review date: University Ethics of Research Committee 15th March 2023 Contact: research-ethics@bristol.ac.uk Approved by University Research Committee via Chair Action on: 18th May 2023

Appendix 2:

Revised Ethics of Research Policy and Procedure

Version 9.1

Version 9.1. Amendments made throughout by Matthew Brown. Circulated to UERC members for electronic comment, 18.4.24. A clean version will be produced on 24.4.24.

Version 9.2. Amendments made throughout by Matthew Brown, Adam Taylor, Liam McKervey, 30.4.24, MB_AT_LMK

Version 9.3. Clean version, 30.04.24, MB_AT_LMK

University of Bristol Ethics of Research Policy and Procedure

The University aims to create a culture of dialogue, openness and collaboration in Research Ethics, and to become a centre of excellence in this area.

This Ethics of Research Policy and Procedure enables the University's Vision and Strategy which aims to 'ensure inclusion and equity in how we do research with others [so as to] nurture and enable an environment that creates a virtuous circle of quality, reputation, knowledge exchange and impact – including transformative impact on the global research ecosystem'.

The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, the welfare of animals and the integrity of the environment. The University is also concerned to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research.

This document is written to further those ends and to comply with the legitimate requirements of outside research funders and collaborators.

1.University Ethics of Research Committee

University Ethics of Research Committee (UERC) exists to promote a culture of dialogue, openness and collaboration in Research Ethics that will make the University of Bristol a centre of excellence. The Committee is responsible for oversight of research ethics across the University, and is tasked with encouraging and facilitating best practice. UERC's oversight responsibilities are both strategic and operational. These are detailed in UERC's Terms of Reference.

2. Types of research

All research requires consideration of its ethical implications, whether for its potential consequences upon the researchers themselves, human or animal participants, the environment or where the nature of a project, partner or source of funding could be a risk to the University's reputation or position as a publicly funded charitable body. Research Ethics Committee review is required for all research involving human participants. Research ethics review may be required for research involving human data or human material; serious health and safety implications; animal use; where there is a

risk of damage to the environment; where the impact of the research may be emotionally damaging; where the research is politically or socially sensitive and, or where an appropriate body or individual in the University deems it to be appropriate.

3. Researchers

The University expects all researchers to consider fully the current and future ethical implications of their work. This procedure applies to everyone carrying out research under the auspices of the University, whether their current place of work is within or outside University premises. This includes, but is not limited to, all University staff, visiting researchers, those with honorary posts and registered students. It is the responsibility of the principal investigator of a project to ensure that all researchers involved in the project (including external and international collaborators) are aware of and comply with the policies of the University.

4. Faculties

Each faculty is required to:

❖ draw up guidelines for the ethical conduct of all research undertaken under the auspices of the faculty, appropriate to the academic disciplines within the faculty and in accordance with recommendations made by relevant outside bodies.

❖ ensure that staff and students in the faculty have adequate training in the ethical and appropriate conduct of research

❖ interact with the appropriate procedures for seeking a Research Ethics opinion for all research in the faculty, through the University ethics structure or, where appropriate, through NHS or other Research Ethics Committees outside the University

❖ appoint a named member of staff to act as the Faculty Research Ethics Officer (FREO)

❖ through the FREO, report annually (before 28 February each year) to the University Ethics of Research Committee on research ethics activities within the faculty and their operation, with particular attention to training, sharing best practice and reporting of research ethics breaches

❖ refer emerging issues or particular cases to the University Ethics of Research Committee, through the FREO where they deem it necessary or of interest to the wider University

5. Research ethics committees

UERC oversees a system of Research Ethics Committee Workstreams to review applications. A properly constituted research ethics committee shall have formal terms of reference, membership and standing orders.

Research Ethics Committees will form part of four Workstreams, allocated through use of the Online Research Ethics Management System (OREMS). Workstream 1 will deal with most staff and postgraduate applications. Workstream 2 will cover most Masters and Undergraduate applications. Workstream 3 will be a secondary data panel.

Workstream 4 will enable bespoke panels to be formed for irregular or innovative projects where extra expertise may be necessary.

The Research Ethics Committees operating within these four workstreams might be able to:

❖ delegate authority to sub-committees to review research proposals to provide an opinion

❖ confirm that research satisfies ethical requirements

❖ carry out quality control checks on a proportion of those studies reviewed by sub-committees or individuals

❖ require clarification or modification of parts of a research submission

❖ authorise significant deviations from any approved research proposal

❖ defer consideration of a proposal

❖ reject a research proposal as a whole or in part

❖ revoke a favourable opinion of research if dissatisfied with the conduct of the research

❖ refer students or staff under the University's research misconduct or disciplinary procedures

❖ refer to the University Ethics of Research Committee as appropriate

The committee should give reasons for its decisions. The committee might call for reports on the conduct of research during the project and on completion. Where a monitoring process in line with funder requirements is in place, the committee should review any issues that might arise from the monitoring process. The committee should review significant deviations from a reviewed project proposal. All decisions must be recorded in a transparent and auditable format using the institutionally-approved method. Applicants themselves, or the supervisors of students applicants, should not take part in decisions that concern them.

6.1. Research in Partnership

Where research is being conducted by members of staff or students in more than one institution, the research should seeka formal research ethics committee opinion in one of them. The decision on which is the most appropriate should take into account the location of the principal investigator and the formal ethics review structures in place in each institution. If ethics approval is given by another institution, this does not remove the responsibility of researchers to comply with the University's ethics policy. The Faculty Research Ethics Officer should be kept informed of the outcome of any ethics review carried out elsewhere.

All researchers must comply with national statutory requirements for ethics review by a properly constituted research ethics committee set up in accordance with applicable laws (i.e. under Home Office, Department of Health and Social Care, international guidelines (e.g. ICH-E6) or Human Tissue Authority regulations) . An ethical approval obtained elsewhere is normally acceptable for University purposes. Repetition of research approval is not advised, but Research Ethics Committees may wish to consider additional ethical issues that are specific to the University, as appropriate.

6.2. Research under the Official Secrets Act

Where research is being undertaken under the Official Secrets Act this does not negate the need for an ethics review. Faculties should consider how they would appropriately review any such work whilst complying with the terms of the Act. Faculty, school or unit research ethics committees may delegate authority to a sub-committee of staff who are also bound by the Act but who have an understanding of the faculty and University ethics policies. A senior member of the University with appropriate security clearance will provide oversight for this process and will report annually to UERC on the numbers of research projects being carried out in this area.

6.3. Global Research

The University's vision is that 'international collaboration is a core ingredient of research scale, international reputation and civic impact' and its strategy envisages that the University will become 'a model global civic institution powered by our sense of place and connections to communities'.

Equitable partnerships should be at the heart of research conducted internationally, in line with the University of Bristol's commitments under the [Africa Charter](#). When working in fields characterized by significant power imbalances, in their collaborations Bristol researchers should seek, 'as a first and preferred option, intellectual and institutional leadership' from partners in the place being researched.

In line with the *[Four Approaches to Supporting Equitable Research Partnerships](#)* and its specific recommendations on Research Ethics, Bristol researchers and Research Ethics Committees will bear in mind:

- the differences in ethics review processes between institutions, and will be mindful of the extra hurdles partners may face, particularly in Low to Middle Income Countries;
- that they should ensure that all parties agree on which ethics review processes will be followed, and will avoid duplicating or undermining partner institutions' ethics approval processes;

I   - identify any additional measures needed and schedule accordingly.

        - Where data and /or human tissue samples are collected outside the UK, therefore, the researcher will normally be expected to have received research ethics approval from a properly constituted and independent ethics committee in the country concerned, where such a committee exists to review the type of research being proposed. It is the responsibility of the researcher to check the requirements for ethics review in the country concerned, to make the appropriate applications and to provide evidence of ethics review having been sought and given. If such review is not available or appropriate (for example because of a lack of resources, institutional weakness, under certain political regimes or for covert research), then such research and the reasoning for not obtaining local ethics approval must be agreed by the appropriate University Research Ethics Committee.

        - All research undertaken under the auspices of the University should meet, as a minimum, the ethics standard required within the University, regardless of its place of conduct. As stated above, researchers must consider fully the current and future ethical implications of their work. When working internationally, researchers should seek the appropriate forum to discuss and receive approval from institutions, communities and participants. It may be possible for partner institutions to conduct research ethics processes independently and apply these to joint projects. UERC will

convene bespoke panels of experts to develop and update guidance on research ethics approval and monitoring for international collaborative research.

7. Reports to the University Ethics of Research Committee

All Research Ethics Committees, review groups and Faculty Research Ethics Officers will provide annual reports to the University Ethics of Research Committee by 28 February each year. They should identify best practice and make recommendations for improvements and lessons learned from any ethics breaches or difficult cases.

8. Guidance by the University Ethics of Research Committee

Where particular ethical concerns are referred for advice to the University Ethics of Research Committee, by Research Ethics Committees, review groups or individuals, the Committee will request a written statement of the issues, supported by relevant documentation and a summary of the reasons for doubt or disagreement. The Committee may, as it deems appropriate, invite members of the University to attend and make representations and may also seek outside advice. The guidance given shall be recorded in writing and shared appropriately.

9. Appeals to the University Ethics of Research Committee

Decisions on Research Ethics approval may be appealed to the University Ethics of Research Committee. The Committee will not hear appeals until all other processes and remedies have been exhausted. The Committee will consider the reasonableness and fairness of decisions appealed against. The Committee will not hear appeals against the decisions of external ethics committees, which should provide their own appeals procedures. However if a 'Yes' decision to proceed with research is given by an external ethics committee and this is reported (under the University's Public Interest Disclosure Policy) as contravening the University of Bristol's research ethics policy, then the University Ethics of Research Committee can consider this as an appeal for resolution. In exceptional circumstances when, for good reason, issues need rapid consideration, the Chair may act after consultation with no fewer than two members of the Committee who do not have a conflict of interest, one of whom must be an Independent member. The Committee shall be informed promptly of decisions made on this basis. If a member of the Committee is not able to attend the meeting, they may submit written observations on any issue under consideration. Where agreement cannot be reached, decisions are by a majority and in cases of equal votes, the Chair shall have the casting vote. The Committee and the Chair are empowered to take advice from senior University officers, lawyers, or any person in or outside the University with specialist knowledge on the issues in question. The Committee shall be permitted to co-opt specialists to advise its members, when required. Where the faculty does not accept the decision of the University Ethics of Research Committee, the Committee will refer the matter directly to the Vice Chancellor, by means of a written report, through the University Research Committee, for final resolution. Senate and the Board of Trustees will also be notified.

Annex 1.

Role descriptions as approved by UERC in 2023/24

Chair of UERC

The Chair leads the work of the University Ethics of Research Committee (UERC), which oversees research ethics across the University.

The Chair of UERC is conferred membership of University Research Committee. They work with the Research Governance (RG) team, who provide administrative support to UERC, to organize quarterly meetings of UERC and ensure that strategies and action points are delivered.

The chair is supported by a Deputy Chair, with whom they work closely.

The purpose of UERC is to act as an oversight group to encourage and facilitate best practice in research ethics and integrity issues, and in reviewing and overseeing ethical practice in human-participant research. It provides a focal point for the discussion and dissemination of guidance and practical updates and it reports to Senate via URC (Terms of Reference, 2.1).

The Chair is responsible for making sure that UERC fulfils its duties as set out in its Terms of Reference.
It is noted that the Chair of UERC does not bear any personal responsibility for the decisions adopted by UERC.

The Chair of UERC is chosen by a vote of the members of UERC held as part of a UERC meeting or online by agreement, organized by Research Governance. It is expected that the Chair will serve for a term of three years, with the possibility of no more than one further term if agreed in a quorate meeting by a majority of UERC members.

It is expected that chairing UERC will account for approximately 120 hours of the chair's workload in each academic year.

Deputy Chair of UERC

The Deputy Chair is chosen by a vote of the members of UERC held as part of a UERC meeting or online by agreement, organized by Research Governance. It is expected that the Deputy Chair will serve for a term of three years, with the possibility of no more than one further term if agreed in a quorate meeting by a majority of UERC members.

The Deputy Chair may stand for election to the role of Chair at the end of their period of office.

The role of the Deputy Chair is to support the Chair though regular meetings and consultations, and taking on particular actions where reasonable and appropriate as a result of discussion and dialogue. In the unavoidable absence of the Chair, the Deputy Chair will chair meetings of UERC, represent UERC on URC, and liaise with the Research Governance team as appropriate.

It is noted that the Deputy Chair of UERC does not bear any personal responsibility for the decisions adopted by UERC.

It is expected that the role of Deputy Chair will account for approximately 60 hours of their workload in each academic year.

<u>Members of UERC</u>

Members of UERC are expected to deliver the specific duties of the committee as detailed in section 4 of the Terms of Reference. In practical terms this means:

> attending all meetings of UERC, participating in its discussions and working to deliver its specific action points when agreed by the committee (a quorate meeting requires five members of whom one will be an independent member);
>
> working to foster a research environment in which research ethics and integrity issues are firmly embedded throughout the university;
>
> monitoring research ethics and acting as a conduit into UERC for concerns raised by members of the University;
>
> advising other research ethics committees where appropriate through regular meetings, training events and information sharing;
>
> taking part in the regular UERC visits to research ethics committees.

Each member of UERC will serve a term of three years, which may be renewed for a second term with the agreement of the Chair. Members of UERC are appointed by Senate on the recommendation of the deans of Faculties.

It is expected that membership of UERC will account for approximately 50 hours of their workload each year.

It is noted that the responsibilities of UERC members will vary as to whether they are independent members, professional services members or academic members (currently representing the six faculties).

<u>Independent Members of UERC</u>

The University is concerned to protect and develop its reputation as a centre for properly conducted and high-quality research whilst aiming to ensure the health, safety, rights and privacy of research participants, the academic freedom of researchers, the welfare of animals and the integrity of the environment. In pursuit of these objectives, the University has delegated responsibility for advising on, and assuring compliance with, best practices in research ethics and integrity to the University Ethics of Research Committee (UERC). In defining the terms of reference of this committee, the university stipulates that the attendance of an independent member is mandatory for a meeting to be quorate. This document defines the role of the independent member.

Purpose of the Role

The role of the independent member is to bring a wealth of independent knowledge and expertise to discussions and crucially to provide both strategic challenge and an important external / impartial balance of support to the Chair and Committee when it comes to assuring effective realization of the committee's terms of reference. Fundamentally their presence provides additional external and robust oversight for the Senate, Board of Trustees and URC thereby reassuring them that the University's research ethics agenda is not only being deployed but also is effective.

Responsibilities:

> a.   To be rigorous and persistent in ensuring that the UERC exercises its functions effectively, economically, with good governance and in accordance with the Committee's Terms of Reference.
>
> b.   To challenge the UERC where they perceive potentially unethical practices, behaviours and systems or missed opportunities for dissemination of best practice.
>
> c.   To participate strategically and impartially with a distinctive external and independent voice which questions intelligently, debates constructively, challenges rigorously and decides dispassionately, listening respectfully to the views of others, inside and outside meetings.

d.   To contribute lived experiences to the debate and to make their knowledge, insight and expertise available to the UERC as needs and opportunities arise.

e.   To ensure that UERC exercises control over its strategic direction, and that the committee's performance against its strategic and operational objectives is properly assessed on a regular basis.

f.   To act fairly and impartially at all times, in the interests of the University as a whole, using independent judgement and maintaining confidentiality as appropriate.

g.   To provide the Committee with external and impartial oversight – not management.

Appointments made: By the Senate on the recommendation of the Deans of Faculties. It is expected that membership of the UERC will account for ca 5 full days per year, spread over a greater number of separate visits to the University.

Term of office: Three years. Appointments may be renewed for further terms of three years, but the maximum length of service is *exceptionally* nine consecutive years. Members must then retire from the committee for at least three full years before becoming eligible for possible re-appointment.

Remuneration: Appointments to the UERC are viewed in the nature of public service appointments and no remuneration is made, however Independent Members will be recompensed for their travel to and from meetings in Bristol, or can join meetings virtually. It is expected that independent members will attend at least one meeting per year in person.