Research Ethics Committee (REC) Restructure Implementation Plan

Version History – v1.0

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Introduction:

Following URC and Senate approval of the Restructuring Research Ethics paper in June 2024 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 to a single cross-institution system for ethical review. Applications will be divided into 4 workstreams according to the type of proposal rather than which faculty the PI is based in. The following document outlines how this new structure will be developed and implemented across the University.

The restructure will be implemented in two phases:

1. Phase 1 implementation will involve going live with Workstreams 1, 3 and 4. The date for phase 1 implementation is scheduled for June 2025.
2. Phase 2 implementation will involve going live with Workstream 2 in September 2025.

This document will focus on the first phase of implementation.

Task and Finish Group Membership

A REC Restructure Implementation Task and Finish Group was convened to determine how best to implement this new structure between August 2024 and December 2024.

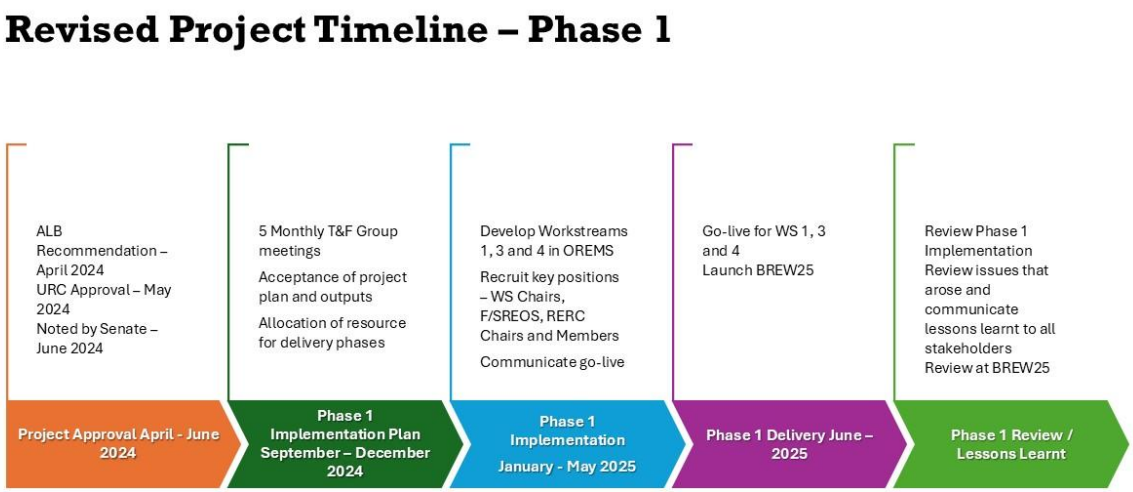
The Research Ethics Committee (REC) Restructure Task and Finish Group is made up of academics and independent members who sit on University RECs from other schools and faculties including, Faculty Education Director and members of the Research Governance Team. The membership of this group is:

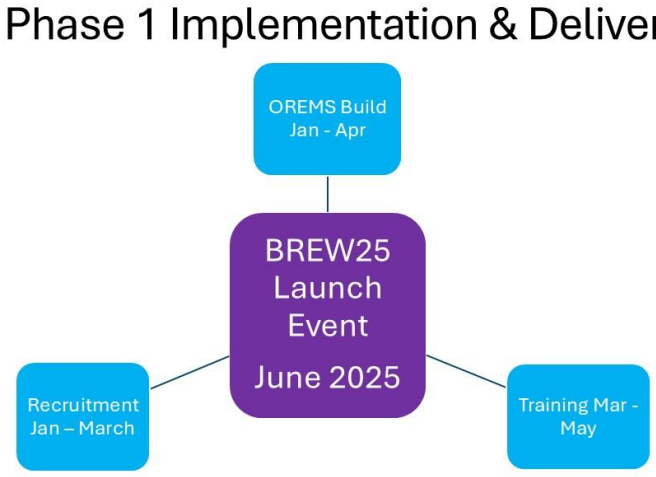
- Professor Matthew Brown (Chair of the University Ethics of Research Committee)
- Professor Ingeborg Hers (Deputy Chair of the University Ethics of Research Committee)
- Professor Vikki Wylde (Co-Chair of the Faculty of Health Sciences Research Ethics Committee)
- Dr Caroline Taylor (Co-Chair of the Faculty of Health Sciences Research Ethics Committee)
- Dr Kayleigh Easey - (School of Psychological Science Research Ethics Officer)
- Professor Andrew Calway (Chair of the School of Psychological Science Research Ethics Committee)
- Dr Jo Rose (Postgraduate Taught Social Sciences and Law Faculty Education Director)

- Dr Anita Mangan (Chair of the Faculty of Social Sciences and Law Research Ethics Committee)
- Dr Nadia Aghtaie (Chair of the School of Policy Studies Research Ethics Committee)
- Ms Kerry Humphries (Faculty of Health Sciences Research Ethics Committee)
- Dr Patricia Neville (Chair of the Faculty of Health Sciences Student Research Ethics Committee)
- Mrs Sarah Vivian (Faculty of Health Sciences Student Research Ethics Committee member)
- Dr David Smith (Independent Members Faculty of Engineering Research Ethics Committee)
- Dr Julian Molina (School for Policy Studies Research Ethics Committee member)
- Professor Mhairi Gibson (Faculty of Arts Research Ethics Committee member)
- Mr Adam Taylor (Head of Research Governance)
- Mr Marc Moyce (Research Ethics Administrator)
- Mx Aisling Marray (Research Ethics Administrator)
- Mr Liam McKervey (Research Ethics and Integrity Manager)

Implementation Timeline:

Phase 1

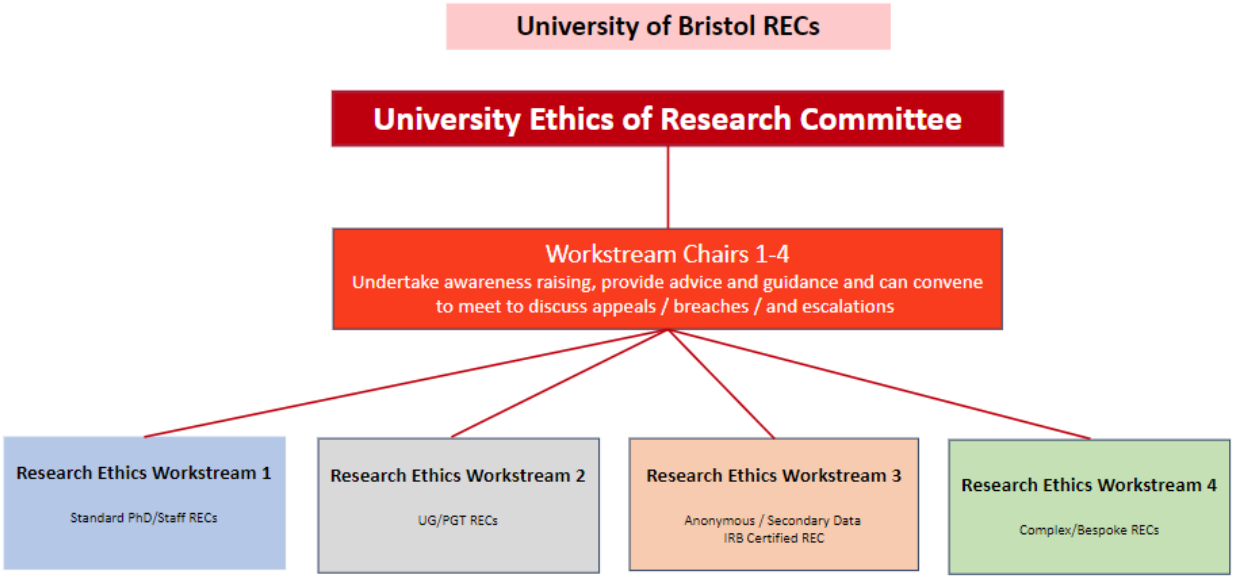




Phase 2

Revised Project Timeline – Phase 2

New Research Ethics Committee Structure:



Workstream 1:

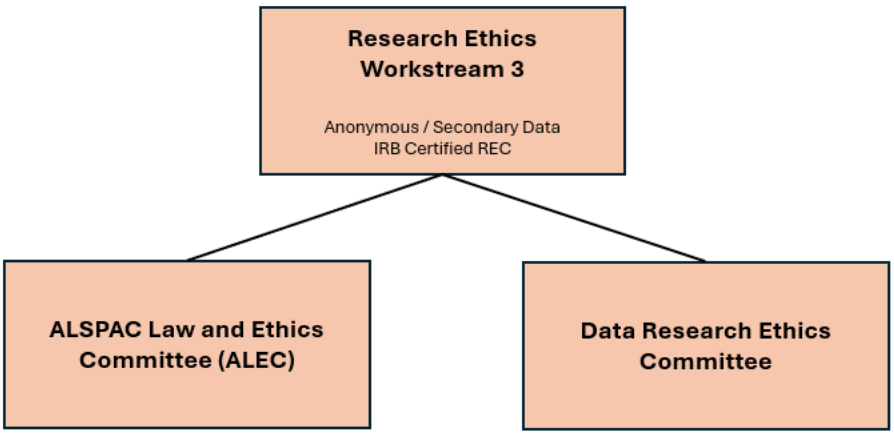
Workstream 1 will consist of 10 Research Ethics Review Committees (RERC), each with a Chair and 8 members including a deputy Chair, an Independent Member and Postgraduate Researcher. These members will be drawn in the first instance from existing Faculty Research Ethics Committees and will have a range of disciplinary expertise. There will be at least one member from each faculty on each Research Ethics Review Committee.

We estimate that 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).

Workstream 1 will have a Chair recommended by the Faculty Pro-Vice Chancellors, whose responsibilities will include:

- Reporting to UERC on the activities of the Workstream as a whole;
- Meet quarterly with the three other Workstream Chairs and the Research Ethics and Integrity Manager to identify issues, identify blockages, find solutions, identify training and guidance needs and share best practice.
- Liaising with the chairs of the WS1 RERCs.

Workstream 3:



WS3 will contain two Research Ethics Review Committees (RERCs):

The ALSPAC Law and Ethics Committee (ALEC):

The Avon Longitudinal Study of Parents and Children (ALSPAC) is a four-generation prospective study. The ALSPAC Law and Ethics Committee (ALEC) comprises clinicians, researchers, and people with legal expertise and lay people, including study participants. The committee meets bi-monthly to consider applications for data collection projects using the ALSPAC cohort. ALEC are deeply integrated into the ALSPAC project, they provide support and guidance considerably beyond the usual remit of an Ethics Committee - to the benefit of the project. As such, it is proposed that ALEC will continue to operate in its current manner.

The ALSPAC Ethics and Law Committee (ALEC) first registered as an Institutional Review Board (IRB) with the Office for Human Research Protections (OHRP) within the United States Department of Health and Human Services in 2003, in order to facilitate ethical approvals for US funded collaborators. IRB status is usually only relevant to US collaborators; exceptionally it is relevant to other collaborators working abroad and University of Bristol researchers seeking access to US datasets.

Federal Wide Assurance (FWA), a perquisite of IRB registration, is provided by the University of Bristol (UoB) Vice Chancellor (VC).

It is proposed that ALEC will retain its IRB status. However, within WS3, a second IRB certified REC will now be convened to manage requests from researchers seeking access

to US datasets, obtaining US Public Health funding (e.g., NIH) or working with US collaborators.

Secondary Data Research Ethics Committee:

The second WS3 Review Group will be established and have IRB certification which will need to be applied for from the Office of Human Research Protections in the US.

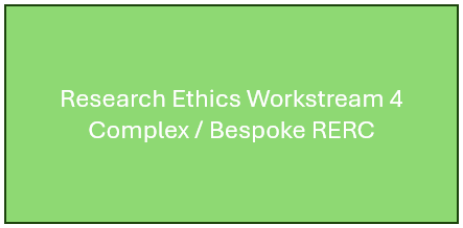
This committee will have data science experience and not be considered as a bio-medical panel. Training will be given regarding ethical issues at an infrastructure level, and which are relevant at a project level.

Its chair will be tasked with developing Standard Operating Procedures to capture consistency, expectations and outcome. The volume of IRB applications will be monitored annually by the Research Ethics and Integrity Manager to determine if it is viable to maintain two IRB certified panels in the medium-term.

Projects qualifying for a WS3 will be routed to workstream 3 if the following applies:

- If a project involves the recruitment of the ALSPAC participant cohort, requiring a review by ALEC only;
- If a project is funded by US Public Health Services requiring an IRB review this will be undertaken by ALEC in the first instance whilst the Research Ethics and Integrity Manager obtains IRB certification for the Secondary Data Research Ethics Committee. Once IRB certification has been obtained, the Secondary Data Research Ethics Committee will review any future reviews requiring an IRB certification;
- If a researcher is seeking access to a US dataset, where an IRB review is required.
- If a researcher is working with a US collaborator requesting an IRB review.
- If the study involves accessing public datasets in line with the Digital Economy Act 2017the research ethics application will be reviewed by the Secondary Data Research Ethics Committee which will operate in line with UKSA guidelines.

Workstream 4:



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, or convening a bespoke panel.

Projects qualifying for a WS4 review should be novel (e.g., Complex tech / AI), ethically complex (e.g, global research projects) or of a magnitude that would exceed the capacity of WS1, 2 & 3 (e.g., EU Funded Large Consortium Bids).

The process flow below outlines the mechanisms for triggering a WS4 review.

There are currently 5 mechanisms identified that can trigger a WS4 review:

1. Prior agreement between the researcher and the Research Ethics Team
2. WS1 Chair request for a WS4 expert / technical input
3. WS1 Chair request for a WS4 full review
4. WS1 Research Ethics Review Committee (RERC) request for a WS4 expert / technical input
5. WS1 RERC request for a WS4 full review

If an application is discussed in advance with the Research Governance Team (RGT), and the researcher has been granted a WS4 Code, the applicant will submit their ethics application on OREMS. By including the WS4 Code, the application will automatically proceed to the WS4 workflow via OREMS. The RGT will then proceed to convene a bespoke WS4 RERC (see below).

If an application is initially submitted to WS1 / 3, once the application has been validated (checked for completeness) by the RGT, the application will be assigned to a RERC. RERC Chairs will undertake an initial review and if they feel that either a bespoke WS4 RERC is required to review an application, they will instruct the RGT to move the application to WS4 and convene a bespoke WS4 RERC.

If in the Chair's view an expert or technical opinion is required, they will instruct the RGT to source an expert reviewer to be co-opted onto the RERC for the review of this application. See 'facilitating an expert / technical review' process below.

Convening a bespoke WS4 RERC:

When convening a bespoke RERC, the Research Ethics Team (RGT), will liaise with the Chair of WS4 to convene a panel. Acting as a WS4 panel member will be considered under citizenship activity rather than formally given workload credit. The panel can / will comprise of the following:

1. *WS1 RERC Chair
2. *WS1 RERC Member
3. Expert panel members drawn from existing members of other RERC panels
4. A panel of expert volunteers registered with RGT
5. An expert co-opted on a one-off basis by RGT. Applicants are invited to nominate an expert in their field in their OREMS application who could be considered for inclusion on the panel, providing they are wholly independent to the research project or proposal.

*We are proposing that WS1 RERC members are included in make-up of the bespoke panel for the following reasons:

Upskilling members – This is an opportunity to upskill members of WS1 to identify and feedback research ethics review undertaken in WS4 reviews.

Applications that are originally reviewed in WS4 as novel, should become the norm as experience in this area grows. Future applications can then be reviewed within the WS1 review process.

Managing longitudinal studies / amendment requests – The proposal for WS4 RERC is that they are stood down once a favourable opinion has been issued. The existing pool of WS1/2/3 RERC members who were involved in the original review of the ethics application will be called upon to review the amendment request or determine if the original WS4 panel should be reconvened to review the amendment request.

People / Committee Constitution:

Terms of Reference

See Annex 1

In the new system, the key stakeholders, roles and responsibilities are:

University Ethics of Research Committee (UERC):

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.

The 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 the University's other RERCs, which report to it. UERC's oversight responsibilities are both strategic and operational.

Faculty and School Ethics Awareness Raising, Guidance Development and Training

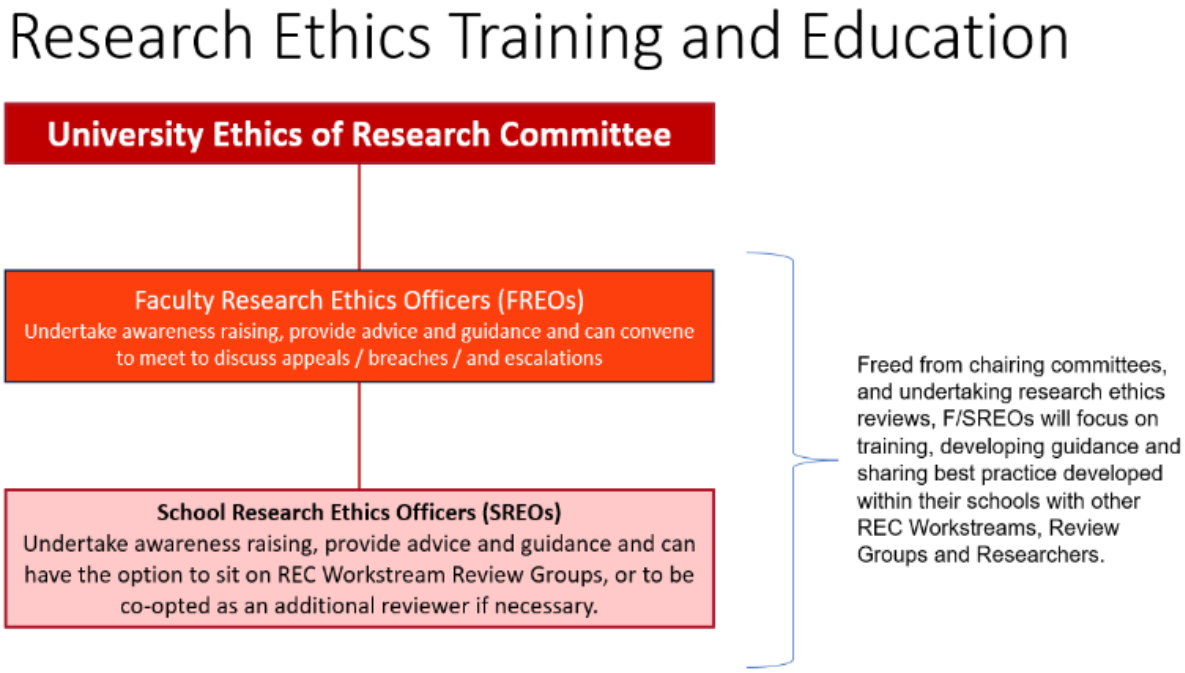
Each of the 3 faculties will have a Faculty Research Ethics Officer who will be in charge of training in research ethics, being the point of contact for the ethical review process and for sharing best practice within their faculty. We recommend that they sit on or report to Faculty Research Committee.

Each School should have a School Research Ethics Officer with the same responsibilities at their level. They can have the option to sit on RERCs, or to be co-opted as an additional reviewer if necessary.

The Faculty / School Research Ethics Officers will not chair committees or approve projects, and are focused on advising, training and sharing best practice.

Faculty / School Research Ethics Officers may be asked to sit on an Academic Integrity Panel in relation to cases brought to panel due to an ethical breach occurring. The Faculty /

School Research Ethics Officer will sit on an Academic Integrity Panel to provide research ethics expertise.



Faculty Research Ethics Officers (FREOs)

- Raise and maintain awareness of research ethics in the Faculty, directly and through the SREOs. Provide advice and guidance, and ensure UERC views are disseminated and decisions implemented;
- Promote best practice within the Faculty;
- Identify training needs within the Faculty, and organise and undertake training as required;
- Prepare written guidance or instructions for the Faculty on research ethics as appropriate;
- Undertake the duties of an SREO if required;
- May attend and report to the Faculty Research Committee;
- Monitor the work of the SREOs and chair quarterly meetings with them;
- Liaise with the Head of Workstreams 1 and 2 over matters of mutual interest or concern;
- Become a member of UERC as a liaison between UERC and their faculty.

School Research Ethics Officers (SREOs)

- Raise and maintain awareness of research ethics in the School, and ensure Faculty and UERC views are disseminated and decisions implemented
- Provide advice and guidance on ethical concerns and ethical application procedures for example guidance to PhD supervisors
- Promote best practice in the School
- Raise issues arising in the School (which require wider consideration) with the FREO
- Participate and contribute to Faculty and School training as requested
- Prepare written guidance and instruction for the School on research ethics as appropriate
- Liaise with other SREOs in the Faculty and meet quarterly with them and the FREO
- Participate in RERC reviews as invited.

Workstream Chairs 1, 3 and 4

Workstream Chairs (who are appointed by UERC from recommendations made by Faculty APVCs) should:

- appoint the Chairs of RERCs
- work to ensure that RERCs in their workstream are following similar guidelines and making decisions that are comparable across the workstream
- keep in regular contact with their RERC chairs, organising quarterly meetings with all of their RERC chairs
- promptly report concerns, queries or differences of opinion between RERC that require resolution, to the Research Governance Team
- report annually to UERC, drawing on reports from RERC chairs. The report should include:
    - an overview of their work over the year, including data, membership, and any issues faced;
    - an analysis of their effectiveness of the sampling carried out by School and Faculty RECs with regard to supervisor sign-off and unit director sign-off as well as standard reviews;
    - any concerns or complex cases, and the lessons learned from them, to the attention of the chair.

RERC Chairs, Workstream 1, 3 and 4

- Undertake Chair's Ethical Reviews of applications, consider PIs' responses and issue decisions
- Resolve issues arising from Virtual Reviews of applications by members of the RERC, and monitor decisions made by the Primary Reviewers, who have delegated responsibility for signing off approvals.
- Chair meetings of the RERC (8 a year), business to include:
    - Discussion Reviews of applications
    - Reviewing a sample of Chair's Reviews identified by the Research Governance staff
    - Sharing experience of reviewing applications and promoting best practice
- Consider PI responses to issues raised in Discussion Reviews and issue final decisions, sending amendments to full committee where necessary
- Provide advice and guidance to RERC members and independent members as required
- Meet quarterly with the Head of Workstream, other RERC chairs and Research Governance staff, to review activity, share experience and best practice and identify issues requiring resolution
- Contribute to the annual report from Workstream 1 to UERC through the Head of the Workstream
- Deputise for the Head of Workstream 1 as requested.

RERC Deputy Chairs, Workstream 1, 3 and 4

- Deputy Chairs' duties may include:
    - Undertaking reviews of Checklist applications, PI Responses, and amendment requests.
    - Deputising on behalf of the Chair in the case of absence.
    - Receive guidance from the Chair in managing the Research Ethics Review Committee.

RERC Members, Workstream 1 and 3

- Undertake Virtual Ethical Reviews as requested, either as Primary or Secondary Reviewer
- When Primary Reviewer, consider PI responses and issue final decision under authority delegated by the Chair of the RERC
- Participate in RERC meetings (8 a year), business to include:
    - Discussion Reviews of applications

    - Reviewing a sample of Chair's Reviews identified by the Research Governance staff
    - Sharing experience of reviewing applications and promoting best practice
- Participate in Workstream 4 Reviews as requested.
- Members of RERCs are tasked with overseeing the maintenance of the highest ethical principles in research from the perspective of multidisciplinary committee. They can seek guidance from disciplinary expertise and from precedent. They are not required to correct grammar or to question methodology, unless they believe that the research in and of itself might be unethical.

RERC Independent Members

- The role of Independent Members of RERCs is the same as Members who are University staff. In particular, Independent Members may be Primary or Secondary Reviewers of applications and may issue final decisions. However, within the RERC they have a special responsibility to utilise their experience and skills from outside the university to encourage the improvement of research ethics in the institution. They are therefore particularly encouraged to air their doubts, question received and conventional thinking and be critical where they perceive potentially unethical practices, behaviour and systems.

Research Governance Team

The Research Ethics and Integrity Manager is responsible for facilitating the implementation and development of the new University ethics structure. They will provide expertise to the Research Ethics Review Committees, to applicants and to other members' and key stakeholders.

Research Ethics Administrators are responsible for offering expert support and guidance to UoB academics and students whose research involves human participants, their tissue and/or data, enabling UoB researchers to engage and comply with UoB's ethics infrastructures.

Notes to the above

In the interest of minimising workloads, resources and timescales for reviews, a number of compromises have been assumed in drafting these role descriptors:

In future, Chairs and Members of RERCs (including Independent Members) will be reviewing applications from anywhere in the University. It is therefore more imperative than ever that submissions from investigators are clear and understandable, in plain English and without the use of technical language and/or acronyms, just as we currently

expect participant-facing documents to be understandable to members of the public. Roll-out of the new review system will be accompanied by guidance to this effect, so that investigators understand that RERCs will immediately reject applications that do not meet this requirement.

To ensure the timeliness of review decisions, it will be important that RERCs have the members available to adhere to the review timetables. It may be advisable for the Research Governance team to maintain notes on Chairs' and Members' availability, and to be in a position to allocate reviews to Chairs or members of other RERCs in someone's absence.

About half of each RERC's Virtual Reviews (with 3 of the 6 members involved) will not involve its Independent Member. This has been considered acceptable given the involvement of the Independent Member in all Discussion Reviews where the most contentious applications will be considered.

While RERC Chairs should be responsible for all final decisions on applications, in the case of Virtual Reviews they will be delegated to the Primary Reviewer.

Workstream 1 Research Ethics Review Committee Composition

Workstream 1 will consist of 10 RERCs, with membership comprising of:

WS1 RERC – 90 Members
Research Ethics Review Committee Membership
Chair
Independent Member
Health and Life Science Member
Health and Life Science Member
Arts, Law and Social Sciences Member
Arts, Law and Social Sciences Member
Science and Engineering Member
Science and Engineering Member
PGR Representation

Recruitment

UERC oversees a system of Research Ethics Committee Workstreams and Review Groups to review applications. The Research Governance Team will manage the recruitment and allocation of members to each Review Group on behalf of UERC.

Research Governance Team

Research Ethics Administrator – Position currently vacant, REIM is engaging with HR to recruit a replacement.

Workstream Chairs 1, 3 and 4

Applications will be open to existing REC members, who will be encouraged to submit an expression of interest to research-ethics@bristol.ac.uk. Recommendations will also be sought from the Pro Vice-Chancellor and Executive Dean for each of the three faculties.

The Pro Vice-Chancellors and Executive Deans for the Faculty of Arts, Law and Social Sciences, Faculty of Health and Life Sciences, and Faculty of Science and Engineering will be asked to circulate the following message on behalf of UERC.

> "Members of Research Ethics Committees can express their interest by sending a brief covering letter (no more than 1,500 words) and a 2 page C.V. to research-ethics@bristol.ac.uk. Shortlisted candidates will be invited to interview. Applicants are asked to discuss their wish to apply with their line-manager before they do so."

The recruitment notice will include the Workstream Chair Role Descriptor

Faculty Research Ethics Officer

Faculty Research Ethics Officers currently in place, will be invited to remain in post. If not, applications will be made open to existing REC members, who will be encouraged to submit an expression of interest. Recommendations will also be sought from the Associate Pro Vice-Chancellor (Research and Innovation) for each of the three faculties.

The Associate Pro Vice-Chancellor (Research and Innovation) for Faculty of Arts, Law and Social Sciences, Faculty of Health and Life Sciences, and Faculty of Science and Engineering will be asked to circulate the following message on behalf of UERC.

> "Members of staff are invited to apply for the position of Faculty of [insert name] Research Ethics Officer in the newly restructured University research ethics process. This vacancy presents an opportunity for a member of the Faculty to engage with the complexities and challenges of research ethics and integrity and to

provide valuable support to our entire research community. The Faculty Research Ethics Officer will lead our efforts to disseminate best practice in research ethics.

The ideal candidate for this role will have extensive experience of research ethics and good research practice; a particular interest in ethical matters relating to human-participant research; and enthusiasm to contribute to the wider University community and to work relating to ethics in research.

Please find attached the role description and key activities for this position.

Further information regarding the restructure can be found on the Research Culture Blog 'A new way for Research Ethics at Bristol'

Anyone interested in applying should express their interest by sending a brief covering letter (no more than 1,500 words) and a 2 page C.V. to research-ethics@bristol.ac.uk. Shortlisted candidates will be invited to interview. The successful candidate will be chosen by an expert panel. Applicants are asked to discuss their wish to apply with their line-manager before they do so"

The recruitment notice will include the Faculty Research Ethics Role Descriptor

School Research Ethics Officer (SREO)

School Research Ethics Officers currently in place will be invited to remain in post. If the post is vacant, applications will be made open to existing REC members, who will be encouraged to submit an expression of interest. Recommendations will also be sought from the Head of School. If a HoS does not wish to nominate a SREO, the responsibilities of the role will be delegated to the School Research Director, in line with their existing Job Description.

"Members of staff are invited to apply for the position of School [insert name] Research Ethics Officer in the newly restructured University research ethics process. This vacancy presents an opportunity for a member of the faculty to engage with the complexities and challenges of research ethics and integrity and to provide valuable support to our entire research community.

The ideal candidate for this role will have extensive experience of research ethics and good research practice; a particular interest in ethical matters relating to human-participant research; and enthusiasm to contribute to the wider University community and to work relating to ethics in research. The School Research Ethics Officer will lead our efforts to disseminate best practice in research ethics.

Please find attached the role description and key activities for this position.

Further information regarding the restructure can be found on the Research Culture Blog 'A new way for Research Ethics at Bristol'

Anyone interested in applying should [insert contact details and application process - e.g. brief letter and CV]. The successful candidate will be chosen by an expert panel. Applicants are asked to discuss their wish to apply with their line-manager before they do so"

The recruitment notice will include the School Research Ethics Officer Role Descriptor

Chair – Research Ethics Review Committee

Anyone currently in position as Chair of a Research Ethics Committee (REC) at Faculty or School level will be invited to become a Chair of a Research Ethics Review Committee in Workstream 1, and 3. Applications will then be made open to existing REC members, who will be encouraged to submit an expression of interest. If we are unable to appoint to each Chair position from existing REC members, we will open the application process to the University.

"Members of staff are invited to apply for the position of Chair of a Research Ethics Review Committee in the newly restructured University research ethics process. This vacancy presents an opportunity for a member of the faculty to engage with the complexities and challenges of research ethics and integrity and to provide valuable support to our entire research community.

The ideal candidate for this role will have extensive experience of research ethics and good research practice; a particular interest in ethical matters relating to human-participant research; and experience with committee processes.

Please find attached the role description and key activities for this position.

Further information regarding the restructure can be found on the Research Culture Blog 'A new way for Research Ethics at Bristol'

Anyone interested in applying should express their interest by sending a brief covering letter (no more than 1,500 words) and a 2-page C.V. to research-ethics@bristol.ac.uk. Shortlisted candidates will be invited to interview]. The successful candidate will be chosen by an expert panel. Applicants are asked to discuss their wish to apply with their line-manager before they do so"

The recruitment notice will include the RERC Chair Role Descriptor

RERC Members

Anyone currently a member of a Research Ethics Committee (REC), will be invited to become a Research Ethics Review Committee member in Workstream 1, 3 and 4. Applications will then be made open to the wider university, who will be encouraged to submit an expression of interest.

Existing RERC members will be provided with the RERC Member Role Descriptor

Workload Credits

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 and Deputy Chairs will be allocated 75 hours.

Further consideration is needed for Professional Services staff who volunteer to sit on a Research Ethics Review Committee (RERC). Consultation with the Director of Faculty Operations will be explored.

Training / Guidance for RERC Members

Training for existing and new RERC members will evolve over time, as the new review process rolled out across the University.

Training provision will initially consist of the following:

- February - March 2025
- Training will be held by the RGT in January for all RERC WS1 and WS3 reviewers
    - This will include clarifying the new RERC review process for all workstreams
    - Escalation routes
    - Who to contact for advice and guidance
    - Role and remit of RERC members
- OREMS Induction process reflecting the new forms
    - How to review and comment on ethics applications

Moving forward we propose to hold three main workshops throughout the academic year:

1. Beginning of TB1
2. Beginning of TB2
3. BREW Event at the end of the academic year

Workstream 1 RERC Member Training

RERC members will be made aware of any additional external training provision offered for example training provided by UKRIO and ARMA.

RERC members can request training via the following mechanisms:

- Request a training topic via
    - the WS1 Chair;
    - F/SREO;
    - RGT.
- Once a theme or topic has been identified, the RGT will work to facilitate training in that area.

RERC members will receive an induction process on

- Identifying key ethical issues in research;
- Embedding a consistent approach to the conduct of ethical reviews.
- Provide forum for RERC members to deliver training to other RERC members:
- Share best practice amongst RERC members
- Discuss complex applications and solutions

Mentoring process for new members

- Existing RERC members could mentor and support new RERC members as they join e.g., being available to answer queries when they are relatively new to the RERC

New RERC Members

Will receive training in the following areas:

- Be assigned a mentor from the existing RERC membership to be available for advice and guidance;
- Overview of the new REC review process;
- OREMS Induction;
- Overview of the key issue in ethics and what to look out for when conducting reviews;
- Who to contact for further advice and guidance.

RERC Existing Members

Will receive training in the following areas:

- Overview of the new REC review process;
- OREMS Induction/Update on changes implemented;
- Overview of the key issue in ethics and what to look out for when conducting reviews;
- Who to contact for further advice and guidance;
- Opportunity to sit on Expert review panel;
- Sharing Best Practice and solutions;
- Opportunity to review PI Responses and Amendment Requests to help upskill RERC members who may wish to take on Chair role

Workstream 3 Research Data Ethics Committee members

WS3 members will receive training in the following areas:

- Specific research data ethics training will be provided for WS3 Reviewers
- Training on IRB requirements will be provided to ensure reviews are conducted in line with the requirements of the Office for Human Research Protections in the US.
- OREMS Induction
    - How to review and comment on an ethics application
    - Updating the OREMS form
- Facilitate training related specifically to data ethics

Workstream 4 Training Provided by Expert Reviewers

To develop the culture of best practice sharing and knowledge capture, the RGT will compile a list of applications that have been escalated to WS4 for review. Any new emerging themes, or topics identified will be collated and the RGT will facilitate training in those areas. At the next available scheduled workshop, WS4 expert panel reviewers will be invited to discuss the ethical issues raised during the review of these application and invited to share best practices and solutions relating to the ethical review of these applications to RERC members. As RERC members receive training in these topics, and become comfortable in reviewing these applications, future applications that have similar issues/themes will now come to WS1 for review. WS4 members will be granted access to previously reviewed and approved ethics applications that would have been considered under Workstream 4.

Workstream 1 RERC Review Schedule

The maximum number of applications reviewed by each Research Ethics Review Committee will be capped at 8. It is noted that 6 full ethics applications for review will be more comfortable. This will be kept under review.

Each Research Ethics Review Committee would only meet once per month, resulting in a maximum of 80 applications reviewed each month. (960 applications potentially per year)

Applications are assigned to a Research Ethics Review Committee on a first come, first served basis.

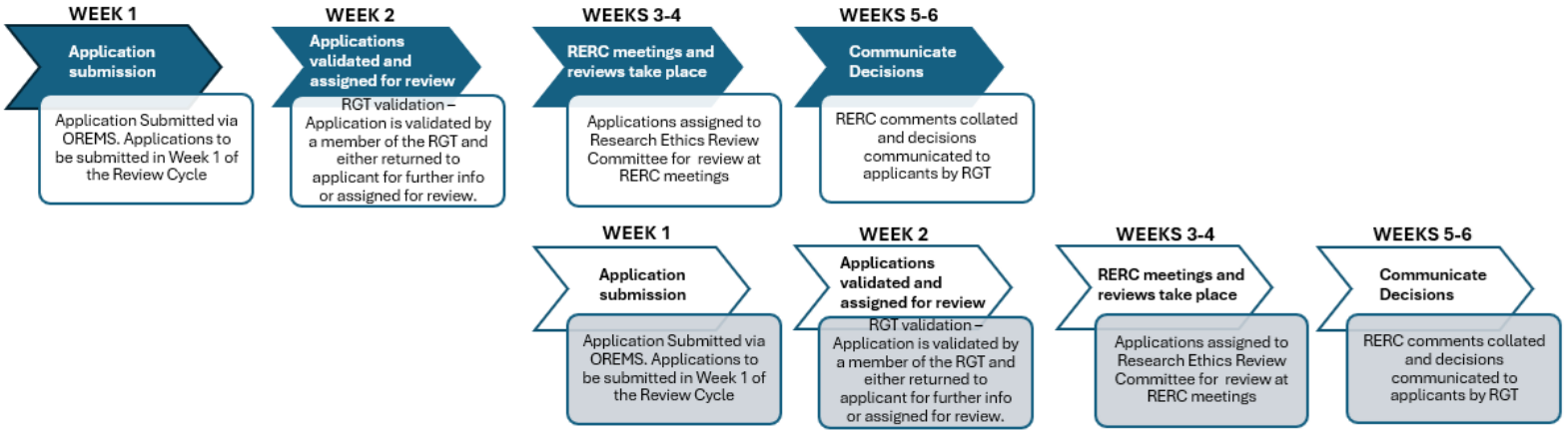
Applications exceeding the maximum number will move into the next available Research Ethics Review Committee for review the following month.

With support from the RGT applications would be evened out across Research Ethics Review Committees prior to review to maintain an even distribution.

The number of Research Ethics Review Committees meetings could vary depending on the number of applications submitted. The frequency of meetings, and application reviews could go up or down.

Staggered 6 Week Review Cycle:

Weeks	2-7	5-10	8-13	11-16	14-19	17-22	20-25	23-28	26-31	29-34	32-37	35-40	38-43	40-45	42-47	44-49	46-51	48-51
Review cycle	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
Dates	6 Jan - 14 Feb	27 Jan - 7 Mar	17 Feb - 28 Mar	10 Mar - 18 Apr	31 Mar - 9 May	21 Apr - 30 May	12 May - 20 Jun	2 Jun - 11 Jul	23 Jun - 1 Aug	14 Jul - 22 Aug	4 Aug - 12 Sep	25 Aug - 3 Oct	15 Sep - 24 Oct	29 Sep - 7 Nov	13 Oct - 21 Nov	27 Oct - 5 Dec	10 Nov - 19 Dec	24 Nov - 19 Dec
Application (2023)	56	41	43	36	34	24	23	29	34	47	23	12	28	23	27	26	48	20
Submission window	2 Dec - 13 Jan	14 Jan - 3 Feb	4 Feb - 24 Feb	25 Feb - 17 Mar	18 Mar - 7 Apr	8 Apr - 28 Apr	29 Apr - 19 May	20 May - 9 Jun	10 Jun - 30 Jun	1 Jul - 21 Jul	22 Jul - 11 Aug	12 Aug - 1 Sep	2 Sep - 22 Sep	23 Sep - 6 Oct	7 Oct - 20 Oct	21 Oct - 3 Nov	4 Nov - 24 Nov	25 Nov - 1 Dec
Application cutoff	56	40	40	40	40	24	24	32	32	48	24	12	32	24	32	32	48	24
Reviews by RERC	RERC 1 - 8	RERC 8 - 8	RERC 3 - 8	RERC 8 - 8	RERC 3 - 8	RERC 8 - 8	RERC 1 - 8	RERC 4 - 8	RERC 8 - 8	RERC 2 - 8	RERC 8 - 8	RERC 1 - 8	RERC 3 - 8	RERC 7 - 8	RERC 10 - 8	RERC 4 - 8	RERC 8 - 8	RERC 4 - 8
	RERC 2 - 8	RERC 9 - 8	RERC 4 - 8	RERC 9 - 8	RERC 4 - 8	RERC 9 - 8	RERC 2 - 8	RERC 5 - 8	RERC 9 - 8	RERC 3 - 8	RERC 9 - 8	RERC 2 - 8	RERC 4 - 8	RERC 8 - 8	RERC 1 - 8	RERC 5 - 8	RERC 9 - 8	RERC 5 - 8
	RERC 3 - 8	RERC 10 - 8	RERC 5 - 8	RERC 10 - 8	RERC 5 - 8	RERC 10 - 8	RERC 3 - 8	RERC 6 - 8	RERC 10 - 8	RERC 4 - 8	RERC 10 - 8		RERC 5 - 8	RERC 9 - 8	RERC 2 - 8	RERC 6 - 8	RERC 10 - 8	RERC 6 - 8
	RERC 4 - 8	RERC 1 - 8	RERC 6 - 8	RERC 1 - 8	RERC 6 - 8			RERC 7 - 8	RERC 1 - 8	RERC 5 - 8			RERC 6 - 8		RERC 3 - 8	RERC 7 - 8	RERC 1 - 8	
	RERC 5 - 8	RERC 2 - 8	RERC 7 - 8	RERC 2 - 8	RERC 7 - 8					RERC 6 - 8							RERC 2 - 8	
	RERC 6 - 8									RERC 7 - 8							RERC 3 - 8	
	RERC 7 - 8																	
New review cycle starting every 3 weeks														**New review cycle starting every 2 weeks**				



Pros:

- Set submission deadlines provide clarity to applicants. Two submission deadlines provide greater option for researchers working under tight timelines.
- Between the submission deadline and application validation process, RGT members have a two-week window to validate applications for completeness, return applications, and advise researchers on what is needed for their ethics application to be submitted for review.
- Reviewers now have a two-week review window, increasing reviewer capacity and addressing availability constraints.
- RERC Reviewers are aware in advance of the review cycle and when they are expected to review research ethics applications. Removing the unpredictability of the ad hoc virtual review process.
- Set timeframe for RGT members to communicate decisions to applicants, providing clarity to applicants as to when they should expect a response.

Cons:

- The process needs to take into consideration annual leave, university closures and peak review periods in which applications that exceed the 80-application monthly capacity need to be reviewed in the next review cycle.
- High concentrated workloads could put strain on the system causing bottlenecks and blockages.
- RGT meeting support is limited and RERC members would need to be tasked with collating responses on OREMS for RGT members to be able to communicate decisions.

Workstream 3 RERC Review Schedule

ALSPAC Law and Ethics Committee (ALEC)

ALEC review process will continue to meet every second month to consider applications for data collection projects involving the recruitment of participants from the ALSPAC (Avon Longitudinal Study of Parents and Children) cohort.

Applications will be submitted via OREMS and filtered accordingly to Workstream 3 and the ALEC via the filtering questions currently in place on OREMS.

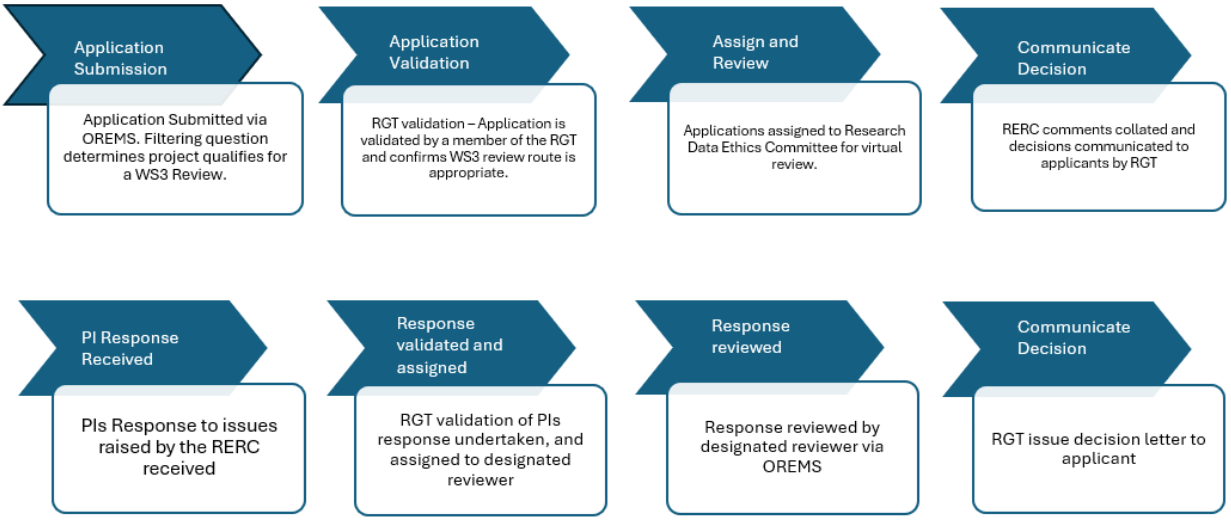
Further information regarding ALECs policies and supporting documentation can be found:

https://www.bristol.ac.uk/alspac/researchers/research-ethics/

Research Data Ethics Committee (Workstream 3)

Ethics applications will be reviewed on an ad hoc basis. Applications qualifying for a WS3 data ethics committee review (see Workstream 3 committee structure above) will be determined by the filtering questions on OREMS.

All applications will be reviewed virtually by the RDEC via OREMS.



Workstream 4

Bespoke RERC

Ethics applications will be reviewed on an ad hoc basis. Applications qualifying for a WS4 data ethics committee review (see Workstream 4 committee structure) will be determined by one of five mechanisms.

The 5 mechanisms are as follows:

1. Prior agreement between the researcher and the Research Ethics Team
2. WS1 Chair request for a WS4 expert / technical input
3. WS1 Chair request for a WS4 full review
4. WS1 Research Ethics Review Committee (RERC) request for a WS4 expert / technical input
5. WS1 RERC request for a WS4 full review

Bespoke panels will be convened by the Workstream 4 Chair based upon the availability of the panel membership.

OREMS Development

The Online Research Ethics Management System (OREMS) is an external Ethics Management system supplied by Infonetica. OREMS has been in use since 2021 and has been implemented across all faculties.

OREMS is a bespoke research ethics management system that can be tailored to reflect the needs of each individual Research Ethics Committee (REC).

Proposal

It is proposed that members of the Research Governance Team will tailor OREMS to reflect the new university research ethics workstreams. This will entail:

1. Liaise with the REC Restructure Task and Finish Group to create an ethics application form for Workstreams 1, 3, and 4. Capturing where possible:
    a. Processes that have been developed in existing RECs
    b. Reducing unnecessary questions
    c. Including clear guidance to aid in the submission of 'good' ethics applications, including sample applications and reviews (redacted where necessary).
2. Develop appropriate filter questions so that the ethics applications are filtered to the appropriate workflow.
3. Create application workflows on the OREMS review side to guide applications from submission to final decision. This involves:
    a. Creating new statuses – OREMS currently has 73 statuses in place to document the status of an ethics application at any given time during the process.
    b. Creating new actions – OREMS Currently has 119 actions in place to manage the submission process for application review.
    c. Creating new tile structures – OREMS currently has in place 29 tile groups, and 267 tiles to manage the visualisation and grouping of applications at any stage of the ethics application process.
    d. Creating new Research Ethics Review Committee groups
    e. Managing access requirements for users – There are currently 194 reviewers requiring the management of their access to review research ethics applications.
    f. Developing document templates – There are currently 127 document templates to facilitate communicating decisions to applicants and alerting reviewers.

g. Each process from a-f needs to function in an interconnected way for the overall process to work effectively.
h. Obtain feedback from existing committee members to implement improvements as part of the OREMS build. For example, SPS REC have requested the following inclusions:
    i. include a subsection on using social media platforms for collecting and/or analysing public data? With pinned guidance'!' to highlight the university's policy.
    ii. incorporating 'EDI issues in research' into OREMS, specifically addressing how researchers consider inclusivity when recruiting participants. The following wording has been suggested by the EDI team: 'How have you considered inclusivity and diversity in the design of this study? For example, please describe the steps you have taken to ensure your participant pool reflects a diverse range of perspectives and avoids unintentional exclusion. If certain identity groups are excluded due to the nature of the research, please briefly explain why. How do your dissemination and impact plans attend to issues of EDI? If you are working with non-academic partners/PPIE, have you been able to consider EDI in relation to this as well?'
    iii. Ensure a unified policy is in place regarding external ethics approvals. Our current policy is that we do not look to undertake dual ethical review, and we encourage a local ethical review were possible.

        If the research ethics approval issued by the research ethics committee in the country concerned covers the UoB researcher's activities on the project, then we would be happy to accept the ethical approval from the external Research Ethics Committee (REC).

        However, we would need to register the ethics application and confirmation of approval for our records via OREMS: https://orems.bristol.ac.uk

        The researcher will be required to upload copies of the approved ethics application study documents as well as a copy of the

favourable ethics opinion (approval) from the external REC for our records.

4. OREMS will need to operate a two-tier review process during the implementation phase. This will include:
    a. Maintaining the existing workflows and processes for existing and legacy ethics applications.
    b. Develop the new process in parallel to the existing process, as we begin to close down existing or legacy applications on the current workflows, we can begin to fully use the new restructure.

Resourcing OREMS Design

To manage research ethics application via OREMS, will require *protected* time to successfully make the necessary changes to the system. The options are as follows:

1. Use existing resource to develop OREMS as an add on to existing job roles. If relying on existing resource, this will need to be done in addition to managing existing research ethics application submissions, reviews, communicating decisions, and supporting committees. Currently the resource in place to design OREMS is as follows:
    a. Research Ethics and Integrity Manager
    b. Research Ethics Administrator
    c. Research Ethics Administrator (position currently vacant)

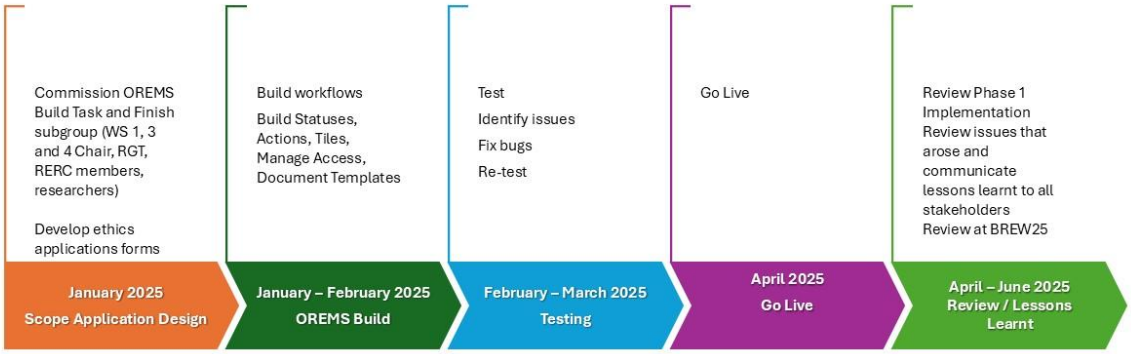
    Risk –This approach could potentially negatively impact the management of existing processes, causing delays, disengagement from researchers and loss of good will in getting researchers to engage with the new process.

    Risk – Without protected time to design and test the new OREMS design, the roll out of the new process could become plagued with issues.
2. Procure resource to backfill support for Research Governance Team members tasked with designing OREMS. This short-term support can facilitate the review of ethics applications, support committees freeing up RGT members time to focus on the OREMS build.

Timeline

Timeline is dependent upon which resourcing option is adopted

OREMS Build Timeline – Phase 1



Managing future OREMS changes and improvements

The Online Research Ethics Management System will remain under continuous improvement. The system will continuously need to evolve to reflect changes within the research landscape, requests from applicants, reviewers and also address technical issues that may arise.

Changes to OREMS will be managed via the following process:

- The Research Governance Team (RGT) will create a OREMS Change Request pro-forma. The pro-forma will be made available to staff and student researchers and reviewers to document any requested changes they would like to see made to the system.
    - The pro-forma will be made available on a centralised research ethics webpage.
- Proposed changes that have been submitted will be collated by members of RGT.
- RERC Chairs, and Workstream Chairs will meet on a quarterly basis to review and discuss proposed changes to OREMS. Decisions will be made on each requested change on whether they will be implemented during this round of changes.
- Decisions will be communicated to the person who requested the change explaining whether the change has been implemented or not. If not, justification as to why the change was not implemented will be fed back.

- Urgent technical issues will be addressed when needed and will sit outside of this process.
- By providing a clear structure of how to request changes, and when these changes will be made will provide clarity and a consistent approach to managing change.

Communication Plan

Introduction

Purpose:

In June 2024, the University Research Committee and Senate approved the Restructuring Research Ethics paper, marking a significant shift in how we facilitate the ethical review of research at the University of Bristol. This communication plan outlines the strategy for effectively communicating the new Research Ethics Committee restructuring across our institution.

The proposed restructure aims to transition from a multi-siloed faculty and school model to a unified, cross-institution system for ethical review. Under this new system, research applications will be categorized into four distinct workstreams based on the type of proposal, rather than the faculty affiliation of the Principal Investigator (PI). This approach is designed to streamline the ethical review process, enhance consistency, and improve efficiency.

Objectives

The implementation of this restructure will occur in two phases:

1. **Phase 1**: Scheduled for June 2025, this phase will see the launch of Workstreams 1, 3, and 4.
2. **Phase 2**: Set for September 2025, this phase will involve the rollout of Workstream 2.

This document details the development and implementation of the new structure, ensuring that all stakeholders are informed, engaged, and prepared for the changes ahead.

Stakeholder Details

Key Stakeholders

Researchers

1. PhD Researchers: Doctoral candidates conducting research involving human participants across all three faculties.
2. Academic Staff Researchers: Faculty members involved in research activities involving human participants.

Research Ethics Committee Members

Individuals responsible for reviewing and approving research proposals to ensure ethical standards are met.

Faculty and School Research Directors

Heads of School

Associate Pro Vice-Chancellors (Research and Innovation)
Senior leaders supporting research and innovation initiatives across the University.

Pro Vice-Chancellor and Executive Deans
Faculty of Arts, Law and Social Sciences
Faculty of Health and Life Sciences
Faculty of Science and Engineering

Stakeholder Needs and Expectations

Researchers (PhD and Academic Staff)

- **Clarity on Changes**: Clear information on how the new system will affect and benefit their research proposal submissions and review processes.
- **Training and Support**: Access to training sessions and resources to help them navigate the new system.
- **Timely Updates**: Regular updates on the implementation timeline and any changes to procedures.

Research Ethics Committee Members

- **Detailed Guidelines**: Comprehensive guidelines on the new review process and their roles within the new structure.
- **Consistency in Review**: Assurance that the new system will maintain or improve the consistency and quality of ethical reviews.
- **Feedback Mechanisms**: Opportunities to provide feedback on the new system and suggest improvements.

Faculty and School Research Directors

- **Impact on Workflows**: Information on how the restructuring will benefit researchers in their schools and faculties.
- **Coordination and Collaboration**: Request their support in communicating information relating to the restructuring to researchers in their schools and faculties.
- **Support for Transition**: How they can help support, promote, and direct researchers to support and guidance.

Key Messages

Core Messages

1. **Aligned Ethical Review System**: The restructure will transition from a multi-siloed faculty and school model to a single, cross-institution system for ethical review, enhancing consistency and efficiency.
2. **Information for applicants:** Applicants should be made aware that they will need to submit their research ethics applications in such a way to take account of the new structure, and that Research Ethics Review Committees will consist of members from a variety of disciplines across the University.
3. **Workstream-Based Applications**: Research applications will be categorized into four workstreams based on the type of proposal, rather than the faculty affiliation of the Principal Investigator (PI), and the vast majority are expected to enter Workstream 1.
4. **Phased Implementation**: The restructure will be implemented in two phases:
    a. **Phase 1**: Launch of Workstreams 1, 3, and 4 in June 2025.
    b. **Phase 2**: Launch of Workstream 2 in September 2025.
5. **Improved Efficiency and Consistency of decision making**: The new structure aims to streamline the ethical review process, reduce bureaucracy, and ensure a more consistent approach across the University.
6. **Stakeholder Engagement**: Continuous communication and engagement with all stakeholders will be prioritized to ensure a smooth transition and address any concerns or questions.
7. **Support and Resources**: Adequate support and resources will be provided to facilitate the transition, including training sessions, informational materials, and dedicated points of contact.
8. **Commitment to Ethical Standards**: The University remains committed to maintaining the highest ethical standards in research, and this restructuring is a step towards reinforcing that commitment.

Communication Channels

Digital Communication Strategy

To ensure comprehensive and accessible communication of the new Research Ethics Committee restructure, we will undertake the following steps:

1. **Review Existing Digital Resources**
    a. **Webpages**: Conduct a thorough review of all existing University webpages related to research ethics to identify outdated information and areas needing updates.
    b. **SharePoint Sites**: Assess current SharePoint sites used for research ethics documentation and communication to ensure consistency and accuracy.
2. **Create a Unified Webpage**

a. **Centralised Information**: Develop a new, unified webpage that will serve as the central information hub for the new ethics review process. This webpage will include:
    i. **Overview of Changes**: Clear explanations of the new structure and its benefits.
    ii. **Detailed Process Descriptions**: Step-by-step guides for submitting research proposals under the new system.
    iii. **Timelines**: Key dates for the phased implementation of the restructuring.
    iv. **FAQs**: Frequently asked questions to address common concerns and queries.
    v. **Contact Information**: Points of contact for further assistance and support.

3. **Integration and Accessibility**
    a. **Navigation**: Ensure the new webpage is easily accessible from the main University website and relevant faculty and school pages.
    b. **Consistency**: Align the content and design of the new webpage with the University's branding and communication standards.
    c. **Updates**: Implement a system for regular updates to keep the information current and relevant.

Internal Channels

Individual / Research Groups/ Others	Optimal way to contact them (e.g., email, newsletter, etc...)	Message/Communication
Bristol Medical School	Bristol Medical School Bulletin (https://uob.sharepoint.com/sites/medical-school) PGR newsletter	
Bristol Dental School	Bristol Dental School Staff Bulletin via Dan McHugh(daniel.mchugh@bristol.ac.uk)	
UoB Business School	Research newsletter (contact business-school-research@bristol.ac.uk) and email from incoming Research Director (Jennifer Johns)	Message needs to highlight efficiency of new process, quell dissatisfaction re OREMS, and emphasize that disciplinary expertise will still be valued. Contact

		Anita for details of the issues.
Faculty of Health Sciences	https://uob.sharepoint.com/sites/health-sciences Individual schools: https://uob.sharepoint.com/sites/medical-school https://uob.sharepoint.com/sites/dental-school https://uob.sharepoint.com/sites/bristol-veterinary School of Anatomy: no page?	
Faculty of Life Sciences	https://uob.sharepoint.com/sites/life-sciences Individual schools: https://uob.sharepoint.com/sites/medical-school https://uob.sharepoint.com/sites/dental-school https://uob.sharepoint.com/sites/bristol-veterinary https://uob.sharepoint.com/sites/psychological-science	
Faculty of ALSS	Sharepoint site currently under development https://uob.sharepoint.com/sites/alss/	via FRD and SRDs
UoB wide	All staff bulletin	

Contingency Planning

To ensure a smooth implementation of the new structure the following back-up mechanisms are proposed to address issues as and when they arise:

1. An extra-ordinary review committee will be convened and called upon if there is a need to undertake an urgent ethical review. The details of this committee will not be communicated widely and will only be called upon in urgent cases. Examples of when an urgent ethical review may be needed are:
    a. An error is encountered during the OREMS submission process, where the researcher had submitted their form correctly, but has not been assigned to a RERC to review due to an error on OREMS;
    b. A member of the RGT has missed the application submission and has not assigned the application accordingly.
2. Dedicated submission clinics will be arranged for researchers to sit with members of the RGT to assist with the submission of their application and assigning application to a RERC.

Annex 1: Glossary

Acronym	Name
ALEC	ALSPAC Law and Ethics Committee
ALSPAC	Avon Longitudinal Study of Parents and Children
BREW	Bristol Research Ethics Workshop
DEA	Digital Economy Act
EU	European Union
FREO	Faculty Research Ethics Officer
FWA	Federal Wide Assurance
IRB	Institutional Review Board
OREMS	Online Research Management System
PGR	Postgraduate Researcher
PGT	Postgraduate Taught
PI	Principal Investigator
REC	Research Ethics Committee
RERC	Research Ethics Review Committee
RGT	Research Governance Team
SOP	Standard Operating Procedure
SREO	School Research Ethics Officer
T1, T2	Term 1, Term 2
UERC	University Ethics of Research Committee
UG	Undergraduate
UKSA	UK Statistics Authority
UoB	University of Bristol
URC	University Research Committee
WS1, 2, 3 & 4	Workstream 1, 2, 3 & 4

Annex 2: RERC Terms of Reference

Research Ethics Review Committee (RERC) Terms of Reference

Drafted by Anita Mangan and Matthew Brown

17 September 2024, updating section 6 of the Ethics of Research Policy and Procedure v.8

1. The Research Ethics Review Committees (RERCs) are governed by these Terms of Reference.

2. **Membership**. As properly constituted research ethics committees they will have formal members and standing orders and must have at least six members, including a chair and one member who is nominated as a deputy chair, and one Independent Member. Each of the University's three faculties should be represented on each RERC. Membership of a postgraduate research student is encouraged. A minimum of 4 members should participate in a Discussion Review. 3 members will be asked to conduct a Virtual Review.

3. RERCs **should**

- only receive applications through the OREMS online platform. RERCs will deal with applications through a designated workstream (1, 2 or 3) as distributed by the Research Ethics Team through the online OREMS platform.
- conduct a thorough review of the documents presented, and issue their opinion (favourable, unfavourable, or requesting revisions) in written form through the OREMS system.
- make decisions having considered and acted upon the declaration of any conflicts of interest (i.e. the involvement of supervisors, line-managers, etc)
- give reasons for their decisions.
- record all their decisions in a transparent and auditable format.

4. RERCs **may**

❖ confirm that research satisfies ethical requirements following review

❖ carry out quality control checks on a proportion (around 10% annually) of those studies in receipt of a favourable opinion from the RERC Chair

❖ require clarification or modification of parts of a research submission before favourable opinion can be granted

❖ authorise significant deviations from any approved research proposal

❖ transfer authority to Workstream 4 review research proposals that they deem as requiring more specialist review

❖ defer consideration of a proposal

❖ reject a research proposal as a whole or in part

❖ call for reports on the conduct of research during the project and on completion.

❖ review significant deviations from a reviewed project proposal.

❖ 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 and/or Research Governance team as appropriate

5. RERCs should **not**

❖ provide guidance to applicants prior to receiving proposals through OREMS (this is the job of School and Faculty Research Ethics Officers and the Research Ethics team through their dissemination of training materials)

6. Faculties should not

❖ repeat any research ethics review that has been conducted by RERCs. Any concerns about RERC processes or decisions should be raised to UERC via the School and Faculty Research Ethics Officers.

7. Coordination of RERCs

❖ The Chairs of RERCs within a workstream will meet quarterly, chaired by the workstream chair, to share best practice.

8. Reporting

❖ In annual reports to UERC, RERCs should report on their procedure, activity, and any issues of concern. Reports should be provided annually by the Chair in the form of a short narrative and participation in the spring UERC meeting.

Annex 3: UERC Terms of Reference

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 and submitted to University Research Committee (noted, May 2024) and Senate (noted, June 2024).

Version 4, this version: Matthew Brown 19/7/2024

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 have a maximum of 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);

• Any 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 and Workstreams.

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;
- The senior member of the University with research ethics oversight of research conducted under the Official Secrets Act
- 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 concerned 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.

Previous 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

This version: Reviewed and discussed by UERC October 2024.

Annex 4: Ethics of Research Policy and Procedure v9.4

Revised Ethics of Research Policy and Procedure

Version 9.4

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, and submitted to University Research Committee (noted, May 2024) and Senate (noted, June 2024).

Version 9.4 produced for discussion at October 2024 UERC meeting, by Matthew Brown 19/7/2024 comments by Liam McKervey added 24.09.24, amendments added by Matthew Brown after UERC discussion 23.10.24, on 24.10.24

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, and maintaining and implementing this Policy and Procedure. 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 participants, animals, 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. In addition, 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

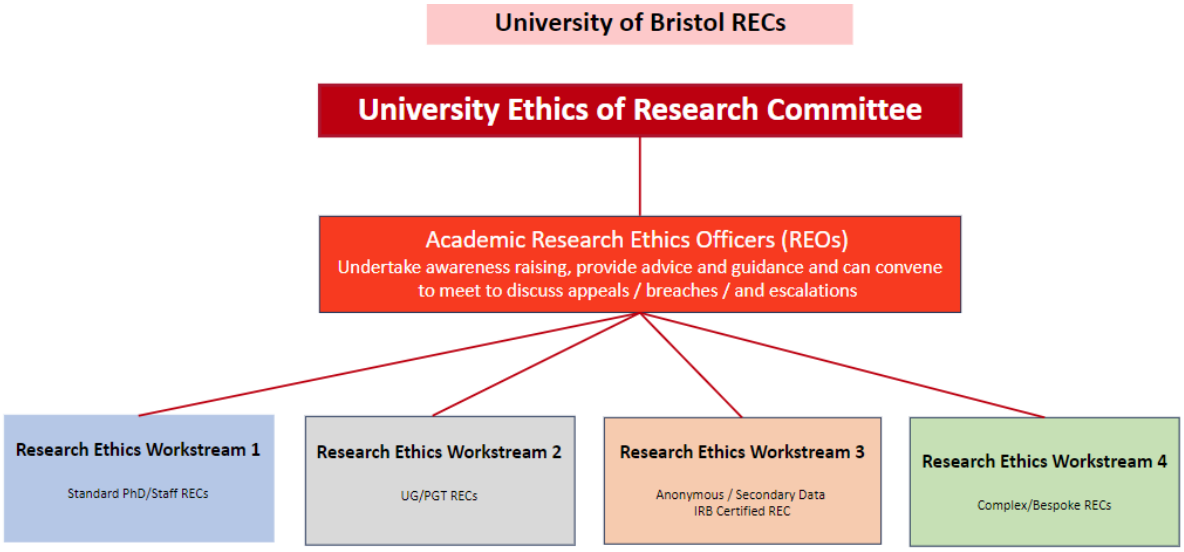
The University expects all researchers to consider fully the current and future ethical implications of their work. This procedure applies to everyone carrying out research under the auspices of the University, whether their current place of work is within or outside University premises. This includes, 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. University-level Research Ethics Committees, Workstreams and Review Groups

UERC oversees a system of Research Ethics Committee Workstreams and Review Groups to review applications. As properly constituted research ethics committees, each

Workstream shall have formal terms of reference, membership, and standing orders. The Research Governance Team will manage the recruitment and allocation of members to each Review Group on behalf of UERC.

Research Ethics Committees will form part of four Workstreams, allocated through use of the Online Research Ethics Management System (OREMS).



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

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.

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

- REC Workstream 1: PGR and Staff Applications
- REC Workstream 2: Undergraduate and PGT Applications
- REC Workstream 3: Secondary-Use Research Data
- REC Workstream 4: Bespoke / Complex Projects

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

Workstream 1: PGR and Staff Applications

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).

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.

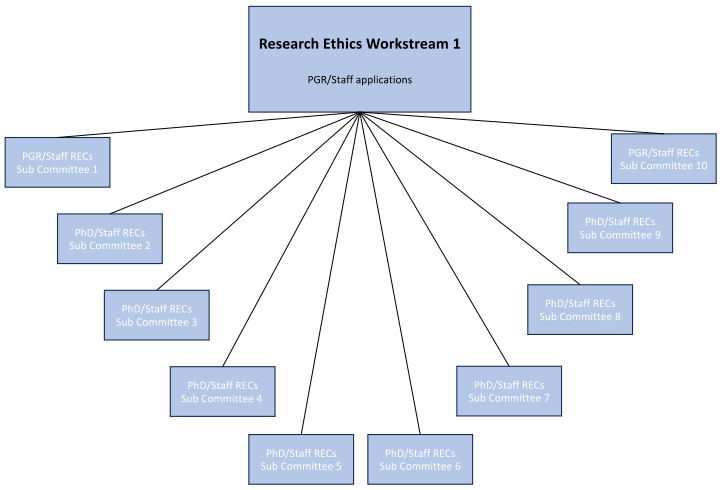
Applications will be assessed by the Research Governance Teams as requiring; Chairs Review, Virtual Review or Discussion Review:

Chair's Review
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.

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.

Virtual Review
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.

Discussion Review
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.
It is recommended 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. The recommendations for workload credits will remain under continuous review and monitored by UERC.



Workstream 2: Undergraduate and Postgraduate Taught Applications:

WS2 will coordinate the review of all applications for research Ethics approval from Undergraduates and Postgraduate Taught students. Because of the distinct educational function of WS2, Schools will organize the review of their students' applications, according to existing procedures from the following suite of current ways of working:

- 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
- Supervisor Sign-Off for Dissertations as is currently done in the School of Arts, and the School of Humanities
- Supervisor and Dissertation Convenor approvals as is currently done in the School for Policy Studies
- Blanket Unit Approvals as is currently done in the Faculty of Engineering

Schools' processes will be monitored and reviewed by the University-wide Workstream 2. Any WS2 applications which need more extended consideration before approval will be escalated to one of 2 university-wide WS2 Review Groups.

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.

It is recommended 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.

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

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.

Workstream 3: **Secondary-Use Research Data**

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

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

A new WS3 Review Group will be established in 2024/2025 and will apply for 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 by UERC to determine if it is viable to maintain two IRB certified panels in the medium-term.

Workstream 4: **Bespoke / Complex Projects**

WS4 deals with particularly complex or pioneering projects, drawing members from WS 1-3 when deemed appropriate, and from a register of experts with experience in the field where necessary maintained by Research Governance. Former members of Research Ethics Committees will be invited to join this register when their periods of service are completed.

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

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

The Research Ethics Committee Review Groups operating within these 4 workstreams are able to:

- confirm that research satisfies ethical requirements
- carry out quality control checks on a proportion of those studies reviewed by Review Groups, sub-committees, or individuals
- require clarification or modification of parts of a research submission
- authorise significant deviations from any approved research proposal
- delegate authority to other committees or Review Groups to review research proposals to provide an opinion
- 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

Committees and Review Groups will give reasons for their 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.

5. Faculties

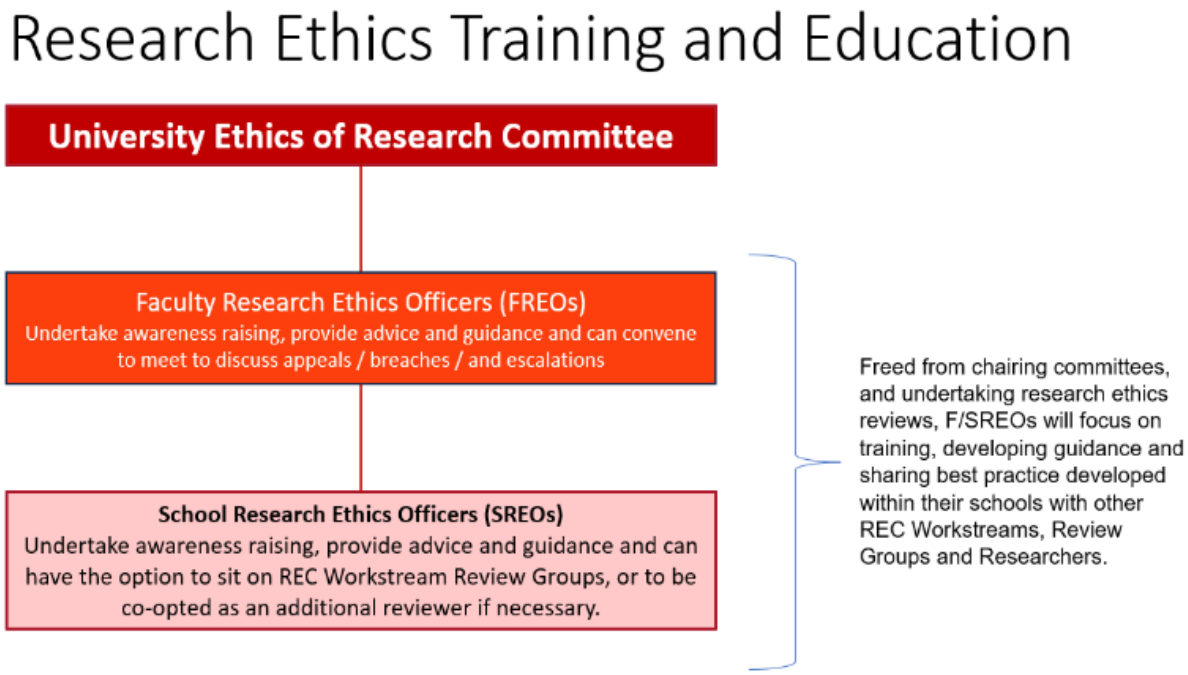
Each of the University's three faculties is required to:

- draw up and maintain 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) and ensure that each School has a nominated Research Ethics Officer
- 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

Responsibilities of Faculty Research Ethics Officers

Each of the 3 faculties will have a Faculty Research Ethics Officer 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 may sit on or report to Faculty Research Committee.



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.

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

It is recommended that the Faculty Research Ethics Officers are allocated 100 hours of their workload per year, and the School Research Ethics Officers 50 hours.

School Research Ethics Officers

Each School should have a School Research Ethics Officer 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.

The School Research Ethics Officer will be the first point of contact for staff, postgraduates, and undergraduates in the School, and will develop and implement School strategy on research ethics for Postgraduate Taught and Undergraduate students, where appropriate.

6.Research in Partnership

- Research involving multiple institutions

Where research is being conducted by members of staff or students in more than one institution, the research should seek a 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 of Bristol's research ethics Policy and Procedure. The Research Ethics and Integrity Manager should be kept informed of the outcome of any ethics review carried out elsewhere. Confirmation of approval should be registered on the Online Research Ethics Management System.

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.

- Research under the Official Secrets Act

UK Government data is classified under the Government Security Classifications Policy (GSCP) and subject to the Official Secrets Act. Whilst everyone in the UK is bound by the

Act, access to, and in some cases knowledge of, this data additionally requires a minimum of Baseline Personal Security Standard (BPSS) vetting.

Where research is being undertaken under the Official Secrets Act this does not negate the need for an ethics review. Faculty Research Ethics Officers (FREOs) should consider how any such work can be appropriately reviewed whilst complying with the terms of the Act ensuring that all staff and students (academic and professional services) with access to and knowledge of the work hold appropriate vetting. For Taught Masters and Undergraduate research projects, a Faculty or School Research Ethics Committee 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. For Staff and PGR work, a FREO can recommend the creation of a bespoke Workstream 4 Research Ethics Committee to review the proposed work, composed 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 vetting will provide oversight for this process and will report annually to UERC on the numbers of research projects being carried out in this area.

- 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;

- 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 an appropriately 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 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 through Workstream 4 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.

Members of UERC

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).

Independent Members of UERC

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.