Report of the Quality Review Group

to the

Research Ethics Committee and Academic Council

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UL QSU Website	www.ul.ie/quality
QQI Website	www.qqi.ie

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1 The UL Quality Review Process

The University of Limerick (UL) follows an established process for quality assurance (QA) and quality improvement (QI) in line with that originally developed jointly by the Irish Universities Association (IUA) and the Irish Universities Quality Board (IUQB), the latter whose functions are now carried out by Quality and Qualifications Ireland (QQI). The review process involves an approximate seven-year cycle during which each unit works to improve the quality of its programmes and services and undergoes a rigorous self-evaluation prior to a quality review by internationally recognised experts in the relevant field.

The common framework adopted by the Irish universities for their QA/QI systems is consistent with both legislative requirements and international good practice. The process itself evolved as a result of the Universities Act, 1997, in which the responsibility for QA/QI was placed directly on the individual universities. The process now complies with the Qualifications and Quality Assurance (Education and Training) Act 2012, as amended by the *Qualifications and Quality Assurance (Education and Training) (Amendment) Act 2019*. The UL Quality Support Unit (QSU) website (www.ul.ie/quality) provides details on the process.

All units are reviewed against quality assurance standards as described in the tailored quality review guidelines, which is available on the QSU website. The planned schedule of quality reviews is available on the QSU website.

The UL quality review process comprises the following three phases:
1. Pre-review phase, in which the unit under review conducts a self-evaluation exercise and writes a self-assessment report (SAR).
2. Review phase, in which a quality review group comprising external experts, both national and international, review the SAR, visit the unit, meet with stakeholders and produce a report (this report), which is made publicly available on the QSU website.
3. Post-review phase, in which the unit considers and formally responds to the recommendations of the QRG, devises plans to implement them and reports implementation progress to the University Quality Committee and UL senior management.

The recommendations made by the quality review group (QRG) form the basis of a quality improvement plan (QIP) prepared by the QSU for the unit under review. Once the site visit is over, the unit sets about evaluating and implementing the recommendations, as appropriate.

Approximately seven to nine months after receiving the QIP template from the QSU, the head of unit provides a summary overview of progress to the university's Quality Committee. Committee members are afforded the opportunity to discuss and evaluate progress.

Approximately 18 months after receiving the QIP template, the head of unit, Vice President Academic Affairs & Student Engagement, Deputy President Chief Operations Officer and Register or Vice President Research, Dean (where relevant) and Director of Quality meet to formally review progress and to agree on any remaining actions to be taken.

2   Summary Details of Research Ethics at University of Limerick

All research at UL to be undertaken involving human participants (including data collected on an anonymous basis), animals and certain other types of research, as indicated in the REC Application Form Checklist, require ethical approval by a Research Ethics Approval (REC).

The University of Limerick Research Ethics Governance Committee (ULREG) is reported to by five standing RECs: one each from the University's four faculties, and a separate Animal REC.

Principal Investigators and Supervisors have the responsibility for ensuring ethics applications are submitted according to these procedures and signifying their approval for such submissions by signing completed ethics application forms prior to their submission to the relevant REC.

Research ethics in UL is managed procedurally as follows.
1. Applications from researchers seeking research ethics approval are submitted to one of the University's five RECs.
2. RECs meet approximately monthly during the academic year, generally around 10 times per year.
3. Researchers are authorised to begin the activity for which approval is sought as soon as it is given by the appropriate REC.
4. Guidelines as to what types of research activity require ethical approval are detailed in the governance documents associated with research ethics.
5. Decisions of RECs are submitted for ratification to meetings of ULREG and this ratification is a standing item on ULREG agendas. This ratification follows the chair of the relevant REC presenting the tabulated decisions submitted to ULREG to the committee, noting items and/or trends of interest and seeking feedback. It should be noted that this ratification is not required to authorise the research activity of an applicant; given that ULREG meets four times a year, this would place an undue burden on active researchers.

REC chairs and their committees are empowered to a large extent to manage their approvals processes in response to their workload, capacity, and resources. As such, some committees implement processes for "expedited" applications in certain situations as well as processes for group/module-level approvals, Chair's actions, and other exceptional situations. ULREG periodically advises RECs as to their authority in these areas and gives guidance around maintaining rigour and consistency in the implementation of their work.

3   Preliminary Comments of the Quality Review Group (QRG)

3.0   Preliminary Comments of the Quality Review Group (QRG)

First, we would like to thank the many people involved in preparing for and supporting this research ethics quality review at the University of Limerick (UL). We are grateful to the representatives of the range of functions involved in the UL research ethics review system, for their commitment and for giving of their time to providing the QRG with extensive information and opportunities for dialogue.

We are impressed with the commitment to research ethics review and support and the appetite for continuous improvement and change shown by those whom we met. This bodes well for an ongoing process of enhancement that we hope our analyses and recommendations will facilitate.

Recognising that there are already changes underway, notably the consideration of introducing a digital system to support the research ethics application and review process, we have identified several aspects in which we see current practices in need of engaged work to ensure consistency and alignment with best practice across the Irish higher education (HE) sector.

While we acknowledge the clearly evident high levels of enthusiasm and commitment of the Research Ethics Committee (REC) chairs and reviewers and the professional staff that support them, and the importance that informal networking and consultation have in seeking to develop and deliver a competent and facilitative service to researchers and students, we also see this reliance on good will as a potential risk. Given the crucial importance of high ethical standards in research for participants, groups and communities, for researchers and for the institution, we are of the opinion that greater recognition in terms of workload allocation and support resources should be given to the ethics review functions, and to the important work of educating and supporting researchers and students. At the same time, research ethics review and support need to be seen as coherent with a broader institutional commitment to ethics, including seeing research integrity as an inseparable element. This suggests that more attention could usefully be paid to further development of explicit institutional cultural norms for research.

The background of progress in national and international approaches to research ethics and the practices of review mandate a vigilant and adaptive institutional mindset. Our judgement is that the University of Limerick has this mindset and will need to ensure that it maintains this and translates it into ongoing, coordinated and systematic evaluation and development of the structures and processes that support high ethics standards in research.

4 QRG Commendations and Recommendations

4.1 Commendations

The QRG commends the following:

1.	The quality and functionality of the existing research ethics review infrastructure at UL, particularly given the high and increasing number and diversity of research ethics applications reviewed.
2.	The impressive commitment of all key stakeholders – including the chairs of the University of Limerick Research Ethics Governance Committee (ULREG) and RECs, reviewers, students and professional staff – to maintaining and enhancing research ethics standards and practices at UL.
3.	UL's dedicated resourcing of professional support for research ethics through personnel in the Office of the Vice President for Research (OVPR), faculty-based professional staff, the Health Research Oversight Committee and other key personnel (e.g., in the areas of insurance and data protection), whose roles make a significant contribution to supporting ULREG and RECs and the associated processes that underpin research ethics review and support.
4.	The support for research students, evidenced by their expressed positive experience of the research ethics process and its being educative in terms of supporting them to further interrogate and improve their research designs.
5.	The leadership demonstrated by multiple key personnel, including the Vice President for Research (VPR), the chair of ULREG and the REC chairs, to upholding and continuously improving the standards of research ethics review and support at UL.
6.	The evident collegiality that was demonstrated among the different categories of staff and across faculties, which has created a positive environment in which experiences and challenges are shared.
7.	The clear commitment to research ethics of the committees responsible for research ethics review at faculty level, in terms of both upholding standards and also innovating.
8.	The development and application of expedited approvals, technical protocols and module-level approvals.

4.2   *Recommendations*

The QRG recommends the following:

4.2.1   Level 1 recommendations

No.	Recommendation	Commentary
1.	Develop an appropriate funding model to adequately support and further future-proof the research ethics review and support function at UL.	The QRG heard clear evidence of the high and increasing workloads on chairs and reviewers, who give of their time in addition to fulfilling their primary academic responsibilities, and of staff having to deal with high volumes of work with significant peaks and troughs.
2.	Establish a cross-functional working group of stakeholders supporting the institution's research ethics infrastructure, and including students, to identify the requirements that will inform the development and implementation of a digital research ethics application management system.	The QRG acknowledges the diverse manual processes implemented by each of the faculty RECs. There is a sense that these processes work "quite well" and there is some concern that digitising them may have an impact on the flexibility and responsiveness of the committees. While there is broad agreement that there is a need for a digitally enabled streamlined process to support the work of applicants, professional REC support and reviewers, this work needs to be conducted in meaningful consultation with all stakeholders.
3.	Develop formal procedures to guard against overreliance on key personnel and good will and against single points of failure.	The people-focused nature of UL's approach to research ethics is clear, and a community dedicated to research ethics is apparent. Underpinning procedures and processes to support these individuals and the community should be strengthened so that overreliance on particular individuals is mitigated.
4.	Create a community of practice of research ethics professional/admin support, researchers and students to further develop and implement best practices across the faculty RECs.	There are silos of best practice emerging, but for applicants the research ethics application process is not consistent across the faculties. Sharing of lessons learned and best practices, such as further development of FAQs, will improve this situation.
5.	Work with senior management to delineate the role of Academic Council and the Executive Committee in the governance of research ethics review and support at the university. While measures to improve the academic governance within existing resources should be made to Academic Council, where additional resources are required a strategic plan or business case should be developed with the VPR.	ULREG is a committee of Academic Council. It is, therefore, not in a position to determine resourcing, and it has no authority to approve spending commitments.

6.	Review the ULREG terms of reference.	The review could consider, for example, the issue that while RECs have autonomy to introduce distinct practices, which facilitates a welcome level of innovation and flexibility which should be retained, good practices are not necessarily shared, and challenges overcome in one faculty seem to persist in others.
		ULREG terms of reference refer to ratification of REC decisions, when all seem to be agreed that this is in fact a quality control step. Therefore, the objective of this recommendation is to amend the terms of reference to reflect current practice.
7.	Develop a coherent approach to ethics risk assessment.	No standardised approach to risk assessment is evident at a number of levels, from students to researchers and the review process.
8.	In the OVPR, review the overall process for approving research at UL and ensure that: a) Research ethics approval is correctly positioned as one component amongst others; and b) Each component is reviewed by the correct University entity.	Research ethics approval should be a discrete and distinct process. However, the effectiveness of the research ethics approval process means that it has developed accretions over time, such as being a checkpoint to ensure adequate insurance is in place. While the OVPR is positioned to act as an 'air traffic control' for all necessary approvals, ULREG and RECs are not positioned to fulfil this function unless they are being considered with an ethical dimension (e.g., insurance as it relates to the protection of the researcher or research subjects). Encompassing these additional elements as part of the research ethics application process risks creating a false impression that RECs are responsible for overseeing these processes and for approving the overall research case in addition to their proper role, i.e., expressing a favourable/unfavourable opinion on the research ethics application.
		Ethics approval should not be seen as the final 'green-lighting' of a research project but rather as one key element in a range of approvals including insurance, data protection and other matters.
9.	Work with senior management to ensure that membership and chairpersonship of ULREG and RECs is formally recognised in workload allocation models and as an institutional leadership role for academic promotions and is vested in people with appropriate background and experience.	As RECs report to ULREG (within an Academic Council governance channel), the time commitments of REC members are potentially hidden from the view of management. The time commitment required to uphold high standards of research ethics is significant and increasing and should be incorporated into workload allocation models and academic promotions, and reports detailing this workload should be submitted to the University Research

		Committee. Otherwise, this important work may become viewed as a 'professional drag' to be avoided by those seeking promotion. It is also important that the independence of the research ethics approvals process is safeguarded.
10.	In the ongoing negotiations between University Hospital Limerick (UHL) REC, Mary Immaculate College (MIC) REC and ULREG, ensure the efficiency of a shared approach to research ethics review. Seek to agree urgently at the highest level a specific time-bound mandate to conclude the negotiations.	The need to regularise the relationships with UHL and MIC on research ethics matters has been highlighted within the self-assessment report (SAR) and was raised at multiple meetings as part of the quality review. Concluding the regularisation of these relationships appears to be a challenge.
11.	Define the boundaries and overlap between research ethics and research integrity (specifically with regard to research misconduct) and align these across research ethics and integrity policies and procedures, and with national and international developments in research cultures.	There were indications within the pre-visit documentation and during meetings with the QRG that preliminary investigation of allegations of research misconduct are being undertaken by those who have responsibility for research ethics rather than research integrity.
12.	Increase the use of protocols for specific procedures that have been developed and reviewed with appropriate expertise at REC level, and approved and kept under review by ULREG and the relevant REC.	This is intended to ensure the maintenance of consistent high standards across projects using the same procedures.
13.	Develop and disseminate a university-wide code of conduct for researchers.	This is intended to ensure the maintenance of consistent high standards across projects.

4.2.2   Level 2 recommendations

No.	Recommendation	Commentary
1.	Introduce dedicated research ethics training for supervisors to cover supporting research students through the ethics approval process, and record training completion rates.	This is intended to ensure the maintenance of consistent high standards across projects and to facilitate the submission of high-quality applications and reduce the requirement for resubmission.
2.	Document the submission of research ethics applications by PhD students ensuring it is sequenced at the correct point in the journey.	The QRG was provided with assurance that at the point of submission of PhD theses applicants are required to confirm that necessary research ethics approvals are in place. The QRG is of the view that, as

		a formal gate, this is too late in the process, and it should be addressed as part of the progression process.
3.	Review all research ethics documentation, processes and systems to ensure that they are accessible and inclusive for the entire UL research community.	Researchers flagged the complex and overwhelming volume of documentation and guidance required to complete a research ethics application. It was highlighted that this may be prohibitive for individuals with learning difficulties or requiring other accommodations. The QRG recommends that the RECs engage with the Disability Support Service (DSS), the Equality, Diversity and Inclusion (EDI) services and other related services to review and revise the research ethics materials to ensure that they are usable by and accessible to all researchers.
4.	Continue work to expand the small pool of reviewers conducting research ethics reviews through the medium of the Irish language by inviting expressions of interest (EOIs) from the wider institution.	The recent amendment to the Official Languages Act has created some (small but increasing) demand to review ethics applications written in Irish. High-quality research ethics reviews are dependent on the availability of trained, diverse and experienced research ethics reviewers. The QRG has identified the importance of the need to increase this pool of reviewers.
5.	Introduce a common mechanism to ensure that ULREG and the RECs implement all their terms of reference in full.	ULREG and the RECs should provide assurance that all their terms of reference are being implemented. This could take place via the annual report to their parent committees, including an annual reporting template that is aligned to their terms of reference, or via an annual work programme that indicates at which meetings certain items are due to be discussed.
6.	Create and maintain an explicit research data retention schedule in each faculty, clearly delineating the roles and responsibilities of the researcher and the supervisor.	There is a lack of clarity around where responsibility lies for research data retention and deletion among doctoral candidates or researchers. It seems that a situation could arise where a PhD is complete, the researcher leaves the university and research data may be removed (before the five-year retention window has expired).
7.	Encourage an evaluation process for ULREG and the RECs, such as a survey of members, to determine their perceptions of committee performance. Further, encourage self-reflection and development at ULREG and REC level.	This evaluation process could survey, for example: **Terms of Reference** 1. Was the business of the committee consistent with its terms of reference? 2. Does the composition of the committee ensure the right balance of skills, experience and participation? 3. Was the frequency of the committee meetings appropriate? 4. Do you have additional feedback on the committee's terms of reference?

		Briefing Material for Meetings
		5. Were agendas and meeting documents received in sufficient time to prepare for meetings?
		6. Was the meeting documentation sufficiently clear and comprehensive to enable informed decision-making?
		7. In addition to meeting documentation, were you able to access the information you needed to make informed decisions?
		8. Do you have additional feedback on the briefing material?
		Conduct of Meetings
		9. Was time at meetings used efficiently and effectively?
		10. Was the amount of time spent on agenda items appropriate to their significance?
		11. Was the atmosphere at meetings conducive to open and productive debate?
		Other comments
8.	Align the treatment of AI in research throughout research ethics, research integrity and academic integrity policies and procedures.	The QRG was assured that steps are already underway to address AI across these policy domains in a coordinated manner.
9.	Review the ULREG and REC terms of reference to include cross-faculty and external members in their composition.	At present, ULREG has an external member, who currently acts as chair, while external members do not seem to be part of the composition of RECs. External members bring an important, impartial and additional perspective, and this perspective should be provided at REC in addition to ULREG level. The QRG is also of the view that the external member of ULREG can be an ordinary member and not restricted to the role of chair.
10.	Reach agreement on the positions of export control and knowledge security in the research approval process in UL.	There is a judgement call to be made as to whether export control and/or knowledge security should be components of research ethics approval, or whether they are standalone items that should be overseen by another UL entity. In this, the following should be clear:
		a) Export control is a matter of law (as per EU regulations and the Control of Export Acts) while knowledge security is a matter of policy/guidelines; and
		b) Academic freedom is limited as follows under the Universities Act 1997, section 14 (2): "A member of the academic staff of a university

		shall have the freedom*, **within the law,** in his or her teaching, research and any other activities either in or outside the university, to question and test received wisdom, to put forward new ideas and to state controversial or unpopular opinions and shall not be disadvantaged, or subject to less favourable treatment by the university, for the exercise of that freedom."
11.	Develop and publish further guidance on when research ethics approval should be sought for activities that are related to institutional evaluation (e.g., Athena Swan and HR activities).	Where research is undertaken for institutional evaluation or by professional staff for business improvement or research purposes, it can be unclear as to whether or not research ethics approval is appropriate. The development of guidance would require deliberation on this topic, and its dissemination would ensure shared understanding.
12.	Agree on responsibility for evaluating the student experience of the research ethics application process and support, with findings reviewed by ULREG and faculty RECs.	At present it appears that the student experience of the research application process and related support is not systemically assessed and monitored. Challenges and potential solutions may be reported to module coordinators and supervisors, but unless these academic cohorts forward feedback to RECs and ULREG, issues may go unnoticed and unaddressed.
13.	Increase diversity in REC membership and chairs.	This would align with UL's Athena Swan Silver strategy.
14.	Review the requirement regarding supervisors acting as principal investigators (PIs) for student applications to ensure this does not disempower the student researcher.	In nurturing the research culture, student researchers should be empowered, with the support of their supervisor, to take responsibility for their research ethics application.
15.	Recognise in the research ethics review and support processes that risks extend beyond participants, researchers and the institution, to groups, communities, societies, living non-human species and environments.	This is to ensure that mitigation for all risks is properly planned to minimise harm for all involved in and potentially affected by research.

Appendix One

A   Membership of the QRG

Prof. John Oates	Emeritus Professor, Open University
Prof. Ciara Heavin	Chair, UCC Research Ethics Committee
Dr Robbie Roulston	Deputy Chief Operations Officer, Dublin City University
Ailish O'Farrell	Technical Writer, Recording Secretary

B   Membership of Research Ethics Quality Team

Dr Barry Shanahan	Research Governance Officer
Prof. Paul Reynolds	Chair, UL Research Ethics Committee
Ms Lana Hannon	Office Vice President Research