

DISTINGUISHED EDUCATION EXCELLENCE AWARDS

Category: Professional Practice Innovation Award

Section B: Case Study

Title: Development of Ulster University's Research Ethics Management System

Summary: A fully integrated online Research Ethics Management System (REMS) has been developed within the School of Biomedical Sciences for ethical review of research projects, comprising digital submission, Committee review and feedback. Electronic administration of the ethical review process has significantly improved student understanding of the ethical process and reduced time and admin burden for both students and staff. Additional provision has been made for more timely review and dissemination of outcomes for distance learning students through the implementation of a screening process imbedded within the REMS. The fully transparent REMS acts as a repository of all research projects and has been adapted by all Faculties following approval by Research Governance.

Key words: Ethics, Research, Management**What was done:**

*Please give a brief description of the case study including the themes and priorities within **five& fifty** it relates to. Explain why you feel this is an example of novel, enhancing, or innovative practice.*

Excellence in research-informed teaching is a key objective of the School of Biomedical Sciences and ethical approval is the first step in conducting research projects. The School's Research Ethics Filter Committee (FCBMS) comprises 18 members and reviews >200 research projects from Biomedical Sciences and Pharmacy & Pharmaceutical Sciences annually. As Co-Chair of the FCBMS since August 2017, I have continually made improvements to the functioning of the Committee to ensure **operational excellence** for our users (students & staff) whilst minimising Committee burden. To provide an efficient, **financially sustainable**, paper-lite Committee, I led in the co-creation and development of an innovative web-based **Research Ethics Management System** with *Mr Olivier Riche, Business Process Developer* in 2017.

Motivation and aims:

A brief outline of the reasons behind the practice described - its purpose and benefits. What change was it intended to make or problem was it designed to solve? What professional knowledge did you draw from to underpin your rationale?

'Ethical consideration is a central issue in the design of any research project involving human participants, their data or tissue to ensure research integrity and good conduct'¹. Ethical approval is an essential part of the University's Research Governance policy and procedures. The ethics review process is often the student's first involvement with research and serves as an important component of their education as a researcher²⁻³ albeit it can be a daunting experience as confusion or delay with this process can prevent or significantly impact on the commencement of projects. It is important to have a learning environment that encourages active engagement with ethical issues⁴ and it has been acknowledged that the simplification of the ethics review process can create a more positive experience for novice researchers⁵. Indeed, many researchers, particularly students enduring project tight time-frames, state that the bureaucracy surrounding ethical approval is sometimes a hinderance to research⁶. I felt it was essential that this process was made as straightforward as possible whilst maintaining integrity.

Implementation:

An outline of how you carried out the initiative, the approaches you adopted. What professional knowledge did you draw from to underpin your approach?

Whilst the FCBMS previously had an electronic submission system, I recognised that Committee review and feedback remained offline and admin support was substantial. Furthermore, confusion around the type of ethical approval required for projects, particularly student research projects, often led to inappropriate or incorrect applications being completed, leading to delays to commencement of studies.

To address these issues, I led the development of a bespoke online **Research Ethics Management System (REMS)** and made key decisions regarding its functionality, continually tested and evaluated the REMS to ensure an

efficient workflow of the full ethical approval process from submission of projects, through Committee admin, review, feedback, resubmissions, and final approval. I implemented prototyping by key stakeholders (submitters including students and research staff, reviewers, Co-Chairs, admin staff) at critical points, provided demonstrations to students, staff and Committee before final roll out of the REMS in June 2018. The REMS continues to be evaluated and updated with additional functions and feedback from users has been positive.

During the development of the REMS, I took over module coordination of the Applied Research Methodologies module which is taken by >80 Distance Learning (DL) MSc Biomedical Sciences students as the pre-requisite module for the MSc research project. Most of these students are employed within private or public hospital laboratories across the UK and Ireland as well as further afield such as Zimbabwe and The Gambia. Each research project requires ethical scrutiny and appropriate approval dependent on the type of study, research participants and location. Ulster's Research Governance policy is that all projects are reviewed by Filter Committees and either approved (if low-risk) or submitted for further ethical approval as appropriate (e.g. UREC or NHS REC). Previously the review process for these MSc projects commenced in January with some projects still within the system until June or beyond, resulting in significant delays to project starts. Upon evaluation, I recognised that a screening process would reduce time and resources, allowing for quicker review and less confusion by students who sometimes completed incorrect applications. "Active and collaborative learning and participant in challenging academic activities (*such as ethical review*) is key for learner engagement"⁷ with alignment of pedagogical, technical and administrative issues necessary for successfully creating an engaging learning environment⁸⁻¹⁰. Embedded within my teaching practice is the exploitation of digital technologies to enhance the student experience and to provide opportunities for learners to develop their digital skills to maximise their employability^{3,11}. In AY 2018/19, I implemented an Office 365 screening form for DL students to deliver timely high-quality feedback on the ethical approval process for each project¹².

Successes and lessons learnt:

Reflect on what worked well, any particular challenges faced and how these were addressed. Comment on the approach taken to evaluation and understanding the impact and effectiveness of the practice described. What did students think about your approach? Include evidence to support your understanding of its effectiveness. Please also say if you are planning any changes or further developments.

Whilst the DL screening form accelerated the process of review and students received responses by the end of Semester 1, the administrative burden for Co-Chairs had increased. Furthermore, these projects were not contained within the REMS. In AY 2019/20, I decided to fully integrate this screening process within the now well-established REMS, enabling all projects to be screened, feedback returned, responses received electronically, and all documentation archived within the REMS. Importantly, students received a more professional, timely and positive ethical review experience, a vital aspect for these projects involving external stakeholders/collaborators. Implementation of these changes for DL students significantly increased the student understanding of the ethical review process and reduced the time and administration required (>85% of all DL projects now reviewed by end of Semester 1 and all correspondence digitised via REMS).

The REMS encompasses the full ethical review process for all research projects. The innovative system acts as a learning resource for students of the ethical review process with full access to Ulster Research Governance documentation and bespoke guidance for applications. It also acts as a secure repository where students and staff have full access to their research projects. There is full transparency of the ethical approval process, administrative burden is significantly reduced (the Committee no longer requires admin support staff) and the FCBMS operates a paper-less Committee¹³. A key aspect of the success of this system is the continuing technical support provided by Olivier with clear communication of the requirements and understanding of the workflow and end-user feedback essential. Future improvements to the REMS will include addition of project amendments and University-wide adaption of the system.

Transferability:

Is this practice transferable? Have you shared your experiences with colleagues? What would your advice be to others thinking of adopting your approach? Do you have any evidence of colleagues adopting your approach?

I provided REMS demonstrations to Ulster's Research Governance team and other Filter Committees and in November 2018 the University's Research Governance Steering Committee, led by Deputy Vice-Chancellor

(Research & External Affairs), approved adoption and development of the REMS for use across the University, providing significant financial savings by eliminating the need for outsourcing¹⁴. A REMS Working Group was established and with my guidance and experience, numerous Filter Committees including Art & Design, Psychology, Nursing, Communication & Media, Applied Social & Policy Services and Education, amongst others have now adopted the REMS, thereby impacting on procedures across all Faculties and Research Governance. In light of recent Covid-19 restrictions, adaptation of the REMS has increased across Faculties and provided the ideal solution for remote management of ethical review within Ulster.

Further information:

e.g. links to website or publications, materials used, presentation slides, screen shots, testimonials; a couple of quotes from students or staff illustrating the case study would be particularly useful

Ulster University Ethics Management System <https://ethics.ulster.ac.uk/portal/ethics>

The screenshot shows the user interface of the Ulster University Ethics Management System. At the top left is the Ulster University logo. The page title is "Biomedical Sciences Ethics Filter Committee" with a "Logout" button on the right. Below the title is a breadcrumb trail: "School of Biomedical Sciences Portal > Ethics". The main content area has a dark blue header "Ethics Submissions" and a dropdown menu set to "Biomedical Sciences Ethics Committee". Below this, there are three main sections: 1. "School of Biomedical Sciences Ethics Filter Committee" with a note: "Please ensure you have selected the correct Filter Committee from the drop-down menu above." 2. "Biomedical Sciences Filter Committee Meeting Deadlines" with a list: "Deadlines for submissions are: - Wednesday 5th February 2020 (for meeting on 12th February 2020) - Wednesday 4th March 2020 (for meeting on 11th March 2020) - Wednesday 1st April 2020 (for meeting on 8th April 2020) - Wednesday 6th May 2020 (for meeting on 13th May 2020)". 3. Three action buttons: "New Submission" (Create A New Submission, Create New), "My Projects" (Manage my submissions, My Submissions), and "Guidance Notes" (Information For Submissions, Guidance Notes).

“The University processes up to 1000 new applications for ethical approval every year, and a significant number of these, ranging from student projects to major grant-funded research studies and trials, originate in Biomedical Sciences. The Ethics Management System has proven to be an excellent development for staff and students in Biomedical Sciences, streamlining and co-ordinating the submission, review and approval process for ethics applications. In fact, the system is so impressive that other research governance filter committees in Life & Health Sciences and across the three other faculties are seeking to adopt it. It is hoped that in due course all 16 filter committees – and eventually the University Research Ethics Committee – will adopt the system.” **Mr Nick Curry, Head of Research Governance.**

"In my capacity as an Administrative Coordinator in the School of Biomedical Sciences eLearning Support Unit, who supports UG and PG Distance Learning students with their Research Projects, one of the most time-consuming and complicated aspects of administration was the process of students applying for ethical approval, which was required before they could progress to any benchwork. Previously students were confused with the whole process of applying for ethical approval and were unsure why and where they had to apply for approval. However, following the introduction of the new on-line process developed by Dr Mulhern for the School of Biomedical Sciences Ethical Filter Committee, the whole process of students applying for ethics approval has been streamlined, resulting in a very positive student experience as well as saving numerous hours in administration." **Mr Kilian McDaid, Administrative Coordinator, School of Biomedical Sciences eLearning Support Unit**

"From the committee's perspective, implementation of the Ethics Management System (EMS) has streamlined the review process, allowing the Committee to feedback to applicants more efficiently and effectively. In addition to improving the approval process for researchers, the EMS has enhanced the process for receiving ethical approval for undergraduate and postgraduate research projects ensuring the students experience a high-quality system to support their teaching and learning activities. This initiative aligns closely with the 'Academic Excellence' strand of Ulster University's 5&50 strategy by improving the student experience by ensuring the Ulster facilities meet the high quality expected in the students' increasingly digitalised environment." **Dr Julie McClelland, Senior Lecturer and Co-Chair BMS Ethics Filter Committee.**

"Thanks all.... Loving this system!" **Dr Justin Magee, Research Director for Art & Design**

"I recently submitted an ethics application to the Biomedical Sciences Ethics Filter Committee using the new online application process. The process was very simple and took a small amount of time to complete. The forms required for submission are clearly highlighted in the "Forms Area", which made the submission simple and also ensured that all of the forms required for the application were present. The ability to save a draft of the application and come back to it was extremely helpful. It is also useful to have all of my ethics submissions available to access from the portal, which includes all of the documents that were approved by the committee and the committee's comments. In summary a simple and easy tool to use, that makes the ethics application much quicker." **PhD Researcher**

References

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- 2 DePauw KP (2009) Ethics, professional expectations, and graduate education: Advancing research in kinesiology. *Quest* 61(1): 52–58
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- 12 Ulster's Principles of Assessment and Feedback for Learning. https://web.archive.org/web/20170701012146/http://ee.ulster.ac.uk/assessment_and_feedback/
- 13 Ulster University Five & Fifty (2016) Five Year Strategic Plan, Fiftieth Year Strategic Vision 2016-2034. www.ulster.ac.uk/fiveandfifty