Introduction and Context

As a signatory to the Concordat to Support Research Integrity, De Montfort University (DMU) has a responsibility to ensure that all research conducted under the auspices of the university is undertaken with integrity. We set out our commitment ‘to improve accountability, and provide assurances that measures being taken continue to support consistently high standards of research integrity’.

As employers of researchers, and signatories of the Concordat to Support Research Integrity, it is highly desirable to use the UK Research Integrity Office’s Self-Assessment Tool, and publish an annual statement outlining:

- A summary of actions and activities undertaken to support and strengthen the understanding and implementation of research integrity;
- Confirmation that we have provision for dealing with allegations of misconduct and that all procedures follow a transparent, robust and fair process;
- Details of any formal investigations of research misconduct and outcomes.

Through compliance with the Concordat, DMU are able to demonstrate a commitment to promoting good research practice, as set out in the Statement of Governance.

Self-Assessment

Research at DMU covers a wide spectrum of areas, and faculties provide support and subject specific guidance for researchers, including ethical considerations (https://www.dmu.ac.uk/research/ethics-and-governance/research-requiring-ethical-approval.aspx). It is imperative that ethical approval is applied for prior to the commencement of research and routed through the appropriate Faculty Research Ethics Committee (FREC), meetings of which are held quarterly. FRECs report to the University Research Ethics Committee (UREC).

This last year has seen some significant initiatives in our self-assessment process, with an Ethics Task and Finish Group set up to review DMU’s ethics governance structures in September 2019. Chaired by the Associate Dean for Research and Innovation in the Faculty of Health and Life Sciences, the Group put forward a set of recommendations on several aspects of research ethics and integrity, particularly in relation to health-related research and sponsorship, to the Deputy Vice-Chancellor, in February 2020. The group was also tasked with developing a set of recommendations to ensure good governance and compliance with statutory requirements for sponsorship of research studies in line with the UK Policy Framework for Health and Social Care Research.
The review and recommendations put forward by the Ethics Task Group highlighted several key areas of concern, including the lack of robust processes to oversee governance and sponsorship of health-related research, and significant variation in practices across the different research ethics committees. This then led to the Pro-Vice Chancellor for Enterprise and Research (PVC E&R) setting up an Ethics Review Group, led by the Head of Policy, Governance and Research Student Services, to review ethics and governance processes across the spectrum, from undergraduate students through to staff.

The Ethics Review Group will report to the University’s Executive Board via the PVC E&R. Drawing on sector benchmarks, this Group drew up a set of recommendations. It drew attention to the absence of a Research Ethics Code of Practice (RECoP), and as part of its recommendations, put forward a draft RECoP (to replace the more generic and less overarching Research Good Practice Guide), as well as drew up new terms of reference for both the University Research Ethics Committee as well as the Faculty Research Ethics Committees. The group recommended ways to strengthen governance structures, particularly for health-related research, and the creation of Standard Operating Procedures for research sponsorship, including closer monitoring of projects through to completion.

Three further significant recommendations emerging from the Ethics Review Group were:

1. It is not clear how ethics is mandated or managed at undergraduate or postgraduate taught level, or what the sanctions are in the event of a breach of ethics (e.g. data collection from human participants without securing ethics approval first).
2. DMU does not provide mandatory training for research ethics and integrity. Providing such mandatory training is also a requirement for the institution as a signatory to the Concordat on Research Integrity.
3. The need for greater awareness-raising around ethics with a view to capturing projects for ethical review that may not start as research, but might involve data capture that might be used for research further down the line.

The reviews are currently going through the DMU governance structures, with actions and implementation to be completed during academic year 2020/21.

**Systems and Processes**

1. Following a review of ethics application processes conducted by the Faculty Research Ethics Committee (FRECS) during the previous academic year, it became evident that faculties were not operating a single process. The University procured an online ethics application system and work is commencing in November 2020 to implement a unified set of processes across all faculties, and to make a more transparent and auditable system available for all ethics applications (undergraduate to staff) by the end of 2020/21.

2. The constitutions of the Faculty Research Ethics Committees (FRECs) were reviewed and updated with an emphasis on the recruitment of lay members. It was felt that a lay member on the committee would bring an independent voice to the committees and be able to question decisions and processes from an unbiased standpoint. The Faculty of Health & Life Sciences (HLS) successfully recruited a lay member, who is the newly appointed Chaplain for DMU.

3. Terms of reference for the University Research Ethics Committee (UREC) were reviewed and updated to reflect current membership and vacant positions.
4. In Business and Law (BAL) steps are still being taken to examine the quality of research ethics processes for students on placement, as well as students in partner institutions, especially those overseas, to ensure their processes align with those of the Faculty and DMU for programme validations.

5. Members of HLS and the Information Governance Team completed an online self-assessment audit that allows organisations to measure their performance against the National Data Guardian’s 10 data security standards. The audit requires organisations that have access to NHS patient data and systems to complete the Data Security and Protection Toolkit, to provide assurance that they and relevant staff are practicing good data security and that personal information is handled correctly. Submission is due early in the 2020/21 academic year.

Policies and Initiatives

DMU has continued to review policies and guidelines that inform and guide research practice in line with current legislation.

Policies

1. Guidelines on the ethics of research conducted online, and research with children and young adults have been developed and are awaiting finalisation and approval;

2. The Sensitive Research Policy was reviewed and updated to provide clarity on the use of data for evaluation versus research purposes, between handling sensitive data and handling sensitive materials, and extended to cover teaching, not just research.

3. Guidance for researchers on the General Data Protection Regulations as it intersects with research has been developed, and is pending approval.

New Initiatives

1. In response to the global COVID-19 pandemic, all face to face research was suspended and where possible and with approval, moved to online data collection methods. The situation remains under review pending updates from the UK Government.

2. In December 2019, UREC approved a process to allow for Exceptional Block Approval, at the module level, for undergraduate programmes that require ethics approval. The Block approval is for a maximum of three years in each instance, and can only be given to groups of projects in a module that follow the same protocols and are very low risk. The process also allows for random audits of projects that have gained Block approval to ascertain that they are not veering off the standard protocols, that ethics approval has been granted for.

3. Online webinars were launched to inform both academic researchers and PhD students of the importance in completing Data Protection Impact Assessments.

4. Ethics training has continued within Faculties, including online presentations for GDPR, Data Protection Impact Assessments and Data Storage. A new virtual training session was launched for PGRs and academic researchers that covers Research Ethics and Integrity, which is being offered once every two months. In the wake of the COVID-19 pandemic, the
session has moved entirely online, and has had an attendance of approximately 30 staff and students at each session.

5. Work was begun on updating the DMU webpages for Ethics and Integrity, which will allow for greater transparency of policies and processes, and make key documents more visible and accessible to staff and students. Work will continue during the next academic year.

Investigations of misconduct during academic year 2019-20

DMU clearly states that “within a framework of good governance and appropriate training, responsibility for the conduct of ethical research must ultimately lie with the researchers themselves.” DMU has in place a Misconduct in Research – Investigation Procedure to allow for allegations of research misconduct to be investigated in a fair, objective and confidential manner, by implementation of a three stage process: (i) preliminary consideration, (ii) screening and (iii) formal investigation. Informal resolution (without the need for formal investigation) may be appropriate for allegations that are not considered of a serious nature.

Staff Case: Serious Peer Review Irregularities

SAGE Publishing contacted DMU about two papers under investigation, both of which had a peer reviewer listed as being at DMU. For both articles, this peer reviewer had been found to have used the same computer to submit peer reviews as the author had used to submit the original articles.

The ADR in this case initiated his enquiry by checking on the peer reviewer’s affiliation with DMU, whereupon it was established that the reviewer had been a PhD student who had completed and graduated from DMU, but now held a visiting research position due to expire in October 2020.

The case was then escalated, with detailed discussions with HR also involving the PVC R&E. The recommendation was to terminate the visiting contract and close this former student/visiting researcher’s DMU email account with immediate effect. His previous supervisor (current line manager) was also informed of the decision.

Research Student Cases

One case of potential bad academic practice, but due to insufficient evidence, the case was overthrown.

An Academic Office Panel is pending on a student case pertaining to issues with data collection and ethics.