Research Integrity Report 2022-23 – Lancaster University

Section 1: Key contact information

1A. Name of organisation	Lancaster University		
1B. Type of organisation: higher education institution/industry/independent research performing organisation/other (please state)	Higher Education Institution		
1C. Date statement approved by governing body (DD/MM/YY)	24.11.2023		
1D. Web address of organisation's research integrity page (if applicable)	https://www.lancaster.ac.uk/research/research-services/research-integrity-ethics-governance/research-integrity/		
1E. Named senior member of staff to oversee research integrity	Name: Professor Louise Heathwaite Pro Vice Chancellor: Research and Enterprise		
	Email address: louise.heathwaite@lancaster.ac.uk		
	Name: Becky Gordon Head of Research Quality and Policy		
1F. Named member of staff who will act as a first point of contact for anyone wanting more information on matters of research integrity	Helen Brace (Nov 2023-Dec 2024) Acting Head of Research Quality and Policy		
	Email address: b.gordon@lancaster.ac.uk		
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Section 2: Promoting high standards of research integrity and positive research culture. Description of actions and activities undertaken.

2A. Description of current systems and culture

Lancaster requires the highest standard of research integrity from university researchers, irrespective of the source(s) of funding (if applicable), area of research or research group. We are committed to upholding University UK's <u>Concordat to Support Research Integrity</u> and have been a subscriber to the UK Research Integrity Office since 2011.

Research at Lancaster shall be legal and transparent and conducted in line with the principles of accountability and responsibility, honesty, openness and respect, as set out in our <u>Research</u> <u>Ethics Code of Practice</u>. The University has existing policies and procedures that consider the ethical and reputational concerns highlighted below. Individual responsibility and accountability for adherence to these policies and to conducting research that is always legal and transparent rest with the Principal Investigator or PhD Supervisors.

Leadership:

Research integrity is led by the <u>University Research Ethics and Integrity Committee (UREIC)</u>. This committee is Chaired by Professor Malcolm Joyce, Cross-Faculty Associate Dean for Research, and has a representative membership that includes senior individuals from across all faculties as well as a post-graduate researcher, a Research Associate and independent lay members.

UREIC has a core responsibility to foster and develop a culture of ethical research and research integrity in our research community. UREIC has oversight of the core elements of research ethics and integrity including the commitment to the Concordat to Support Research Integrity. The committee's terms of reference include the ongoing review, development and adherence to all policies and guidelines that relate to research ethics and integrity, promoting best practice and good conduct throughout the University, and keeping abreast of externally-driven developments to ensure that the University meets all necessary requirements.

Research Services:

Research Services provides information and guidance relating to the University's research activities at all stages of development, completion, or dissemination. All applications for externally funded research have a designated member of the team to support researchers in the project development. Through this support any ethical, reputational or other concerns can be flagged at the pre-application stage. Additional support teams provide assistance after the award of funding, or for unfunded projects, to help researchers and research teams ensure they are acting with integrity and accordance to all legal and other requirements during their project.

Training:

Training is offered to all research staff and PhD students at Lancaster which covers a range of topics including research ethics, governance and integrity. Specific online research integrity

<u>training</u> is available to all staff and students via our webpages. All staff are required to take, and regularly refresh, mandatory training on EDI, health and safety, mental health awareness and information security.

Researcher self-assessment:

All externally-funded research projects must be costed and approved through <u>ACP</u>, the University's costing and pricing tool and the Principal Investigator (PI) must complete the researcher self-assessment in the <u>ACP governance checklist</u>. PIs and PhD supervisors have responsibility to ensure they assess all their research, including un-funded research that is not logged through ACP, and flag up issues for consideration through one or more established routes (e.g. Faculty Research Ethics Committees) or, seek advice from Research Services.

Funding approval:

The ACP process includes the <u>approval stage</u>. All externally funded applications for research will go to the relevant Head of Department (HoD) for approval. HoDs can view the financial cost/recovery, research partners and researcher self-assessment. At this stage HoDs can raise any concerns before approval. Depending on the size of the application further approvals may be required from the Faculty Executive Dean/Research Institute Director, or for the largest grants the Director of Finance and Vice-Chancellor. Applications requiring institutional match are considered by the University Planning and Resources Group. At any stage of this approval process questions may be raised and the process of approval halted.

Ethical approval:

Ethics committee approval is required for activities that directly involve humans, human tissue, data relating to humans, or other ethical issues that have been raised. It is the responsibility of the Principal Investigator, or PhD Supervisor, to decide whether ethical approval is required.

An application for ethical approval must be submitted to the relevant Faculty Research Ethics Committee (FREC) via our digital approval system <u>REAMS</u>. Approval must be gained prior to any work being undertaken. Details of the internal processes can be found in the <u>Procedures for Research Ethics Approval</u>. FREC review is also a route to raise potential conflicts of interest.

UREIC has oversight of all FREC activity; it makes decisions on applications referred up from the FREC and undertakes periodic reviews of FREC approvals. The total number of FREC applications received 2019-20 to 2022-23 are shown in Table 1, together with those funded projects identified by the researcher as not needing ethical review via the ACP governance checklist.

Table 1: Submitted Research Ethics Applications

	2019-20	2020-21	2021-22	2022-23
Total FREC reviewed	565	542	636	643
FREC review not needed	139	146	206	158

Clinical research sponsorship:

All research projects that require approval from the Health Research Authority gain appropriate ethical review (via either an NHS Research Ethics Committee or relevant FREC) and project sponsorship prior to commencing. Where sponsorship is provided by Lancaster University the process is overseen by, and approval granted by, the <u>Clinical Research Sponsorship Committee</u> and researchers are supported by a Clinical Research Governance Officer. Related policies, procedures and templates are <u>available to researchers on our webpages</u>, table 2 shows the number of sponsored projects over the last four years.

Table 2: Sponsored Clinical Research Projects

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Total sponsored	26	16	23	28

Research due diligence panel:

The University assesses the financial, operational and reputational risk of working with certain research funders and partners and in accordance with our acceptance of external funding policy. This is done through a series of checks to identify and manage risk before an activity is approved to proceed. The due diligence checks are undertaken by the Research Development Officer team in liaison with the PI and research partners. A partner questionnaire is required and a checklist is completed and submitted as documentary evidence to the Research Due Diligence Panel for approval or recommendation. Due diligence checks are a requirement of several research funders including UKRI.

Philanthropic fundraising:

The University has an <u>Ethical Giving Policy</u> for staff engaged in fundraising activities, ensuring that due diligence is observed when assessing whether or not to accept significant benefactions or establish specific philanthropic relationships. A due diligence and review process is overseen by the Director of Development & Alumni Relations and through a <u>Gift Review Panel</u>.

Animal research:

All research on animals, or their tissues, is dealt with by the <u>Animal Welfare and Ethical Review Body</u> (<u>AWERB</u>) in accordance with the requirements of the Animal (Scientific Procedures) Act 1986 (amended 2012). Prior to any work being conducted, each project must have undergone a rigorous and objective review by AWERB, whose membership includes lay persons, scientists and those with veterinary and animal care expertise.

Export controls:

The University engages widely in international research collaboration, global movement of researchers and the exchange of new ideas in pursuit of its mission to undertake excellent research and provide world-class education. However, some of the knowledge held, goods used, and activities conducted by academics and researchers have the potential to be misused and are therefore subject to export control law. Export controls are needed for a variety of reasons, including national security and international treaty obligations. Compliance with export

controls is a serious obligation and the University has a <u>statement on Export Controls</u> and guidance is available to help build awareness and to ensure compliance.

Nagoya Protocol:

Each country has rights over the genetic resources that exist within their country such as animals, plants and organisms as well as the associated traditional knowledge. The Nagoya
Protocol on Access and Benefit Sharing (ABS) is an international agreement establishing a legal framework to govern access to genetic material including the associated traditional knowledge, and ensure that benefits arising from the use of these resources are shared fairly. University guidance is available to help researchers who source or use such material to exercise diligence to ensure that genetic resources and traditional knowledge associated with those resources have been accessed in accordance with applicable access and benefit sharing laws implemented by the source country.

Open research:

The Open Research team in the Library work with our research community to enable Open Research. They champion the notion that scholarly and scientific knowledge (and data) should be shared as early and freely as possible in the research process across all disciplines, both within and beyond academia. By aiding the development of open research skills and practices, we are working towards more reproducible, accessible and rigorous research at Lancaster. Oversight in this area is provided by our Open Research Group with membership including senior academic research leaders from all faculties, Research Services, and the Library.

Other policies relating to research:

Other University policies and procedures impact on our approach to upholding the highest standards of research integrity and individual responsibility and accountability. These include:

- Raising Serious Concerns and Disclosing Public Interest Matters (Whistleblowing)
- Misconduct in Research Procedure
- Code of Practice on Freedom of Speech
- Health and Safety Policy
- Safeguarding in Research Statement and Policy
- Bullying, Harassment and Sexual Misconduct (BHSM) Policy
- Financial Regulations
- Anti-bribery and Corruption Policy
- Rules Governing Outside Professional Activities
- Intellectual Property <u>Policy</u> and Support
- Equality, Diversity and Inclusion
- Sustainability
- Research Data Policy and Data Protection

A full list of all University policies and procedures can be found <u>here</u>.

2B. Changes and developments during the period under review

University committees:

In 2021-22 the University's Research Ethics Committee's terms of reference was expanded to include oversight of all research integrity issues and the group renamed to University Research Ethics and Integrity Committee (UREIC). This expansion was made to further strengthen our research integrity culture and to give single committee oversight of ethics, research misconduct, information governance and meeting the Concordat commitments. UREIC met for the first time in October 2022, and throughout 2022-23, and has an extended membership to provide appropriate oversight for its expanded responsibilities as delegated from and annually reported back to the University's Research Committee.

In November 2022 University Research Committee approved the reconstitution of the Clinical Trials Sponsorship Committee to become the Clinical Research Sponsorship Committee and to expand its remit to include oversight of all research that falls within the remit of the UK Policy Framework for Health and Social Care Research. This is achieved by assessing and approving sponsorship of relevant research projects and providing subsequent oversight of sponsored projects on behalf of the university. In addition, the committee will foster and develop a culture of good clinical research practice within our research community. Following the first meeting of this committee in 2022/23 it was agreed to update the name to the Health and Social Care Research Sponsorship Committee (hereafter Sponsorship Committee) to better reflect its terms of reference.

Digital ethics approvals:

A digital research ethical approval management system (REAMS) was launched across the university in November 2021. This introduced a new process allowing applicants to self-review projects that are deemed as minimal risk following criteria agreed at UREIC. This self-review is conducted via a series of "yes/no/unsure" questions at the start of a REAMS application, if the appropriate answer (yes or no) is given then the project does not need FREC review. A FREC review is triggered by an answer that requires a more detailed answer or any "unsure" answers. Each application reviewed in this way was checked throughout the year by the Research Ethics Officers to ensure the use of this new process was appropriate. Any queries were directed to the relevant FREC Chair for confirmation or referral to the full review process. REAMS is designed to reduce administrative load for applicants, academic reviewers and professional services staff; saving valuable time whilst enhancing the experience for the community to further foster an environment of excellent research integrity. A user survey and system review took place during 2022/23 to identify areas of improvement following a full year in use.

Sponsorship approvals:

The Sponsorship Committee is now the approval route for university sponsorship of clinical projects working with the NHS, previously this was done via FREC Chairs and Research and Enterprise Services. Throughout 2022-23, a proportional review has been developed and tested so that the potential risk level of the project determines the scrutiny that each application undergoes. The lowest-level consists of a Clinical Research Governance Officer (CRGO) review

before being sent for approval, for medium-level projects an academic from the Sponsorship Committee also completes a review, and those projects with the highest-level of scrutiny needed will be reviewed by the full committee following feedback and development with the CRGOs.

NHS England Data Security and Protection Toolkit:

All organisations that have access to NHS patient data and systems must use the Data Security and Protection Toolkit to publish an assessment against the National Data Guardian's (NDG) ten data security standards. Lancaster has completed the self-assessment which provides evidence that the University meets the NDG standards.

Researcher training:

During 2021-22 a survey on ethical training provision for staff and post-graduate researchers across the institution was completed. Recommendations for improvements and sharing of best practice was discussed by UREIC during 2022-23 and two new digital training packages were purchased (1) Research Integrity 2.0, which is an updated version of previous institutional provision and (2) Ethical Research which includes new modules under the headings 'becoming an ethical researcher' and 'research ethics in practice'.

UK Reproducibility Network:

Lancaster became a member of the UK Reproducibility Network in 2023 with UREIC Chair, Professor Joyce, taking the institutional representative role. Through connections with other members of this community we hope to better understand the factors that contribute to poor research reproducibility and replicability. We will develop institutional approaches to counter these in order to improve the trustworthiness and quality of our research.

2C. Reflections on progress and plans for future developments

Digital ethical approvals:

Following the 1-year REAMS review in 2022-23 a report with associated recommendations will be considered by UREIC and changes implemented in 2023-24. It was hoped that work would begin this year to implement changes, but resource issues in the ethics team delayed work by a few months. The final report is due to be discussed in the October 2023 UREIC meeting.

Following the implementation of the REAMS review recommendations, and the refresh of standard operating procedures for clinical research sponsorship review, Research and Enterprise Services will consider whether the sponsorship approval process can be transferred into REAMS. Due to the smaller number of applications for sponsorship this is not a major priority, however the University aims to increase research activity in this area and using the existing digital system could be an advantage for researchers as it would be a consistent pathway to university approvals. This is unlikely to be explored until 2024-25.

Researcher training:

The procurement of a replacement institutional digital integrity training course and a new institutional ethics course is a good step forward in 2022-23 to researchers' seeing these topics as positive and beneficial across the university. It has been recognised that these new provisions need to be well promoted and integrated with existing structures and provision to have a significant uptake. A temporary professional service role to help roll out these packages and align with current departmental and faculty provision will be recruited in the first part of 2023-24 and will also set up functionality to measure uptake of the courses. UREIC will continue to discuss training provision during 2023-24 and whether any modules on the new courses should be recommended to more senior committees to become mandatory for certain groups within the research community.

There are plans in 2023-24 to develop an online hub for the research community to promote all training provisions that are available. The new role will help to develop these pages and also to introduce additional training courses in safeguarding, export controls and research impact that will be targeted to the appropriate members of the research community. Consideration will also be given to how training completion and approval authorities may be linked in the future, and how to ensure that training is provided to the relevant staff members as quickly as possible in key areas that also have legal requirements, for example export controls.

Reimaging research practices to mitigate ethical risks in the digital era:

The University was successful in an £1M institutional bid to Wellcome Trust for improving research culture. The project will start in August 2024 and is titled *Reimagining research practices: towards a sustainable, ethical and inclusive future*. The proposal consists of three overarching but interlinking pillars; of particular relevance in this area is the investigation of mitigations for ethical risks arising from reshaping research approaches in the digital era. As a result of these investigations, the two-year project will develop support mechanisms, new resources, university strategies and policies as appropriate. These will be evaluated and communicated across the University and shared with the wider research community.

Section 3: Addressing research misconduct

3A. Statement on processes that the organisation has in place for dealing with allegations of misconduct

Lancaster is committed to the highest standards of research integrity and takes any concerns raised about the conduct of research undertaken by any staff or research students very seriously. To ensure that both internal staff and students and external individuals feel able to report suspected instances of research misconduct we ensure that all our research webpages are publicly available to encourage an open environment, this includes information about our research misconduct procedure.

The University's <u>Procedure for the Investigation of Misconduct in Research</u> was updated in 2021 in line with the <u>procedure published by the UK Research Integrity Office</u>. It provides a transparent, timely, robust and fair process for dealing with allegations of research misconduct. Other relevant policies and procedure are listed below:

- Raising Serious Concerns and Disclosing Public Interest Matters (Whistleblowing)
- Code of Practice on Freedom of Speech
- Safeguarding in Research Statement and Policy
- Bullying, Harassment and Sexual Misconduct Policy
- Financial Regulations
- Anti-bribery and Corruption Policy
- Rules Governing <u>Outside Professional Activities</u>

In the event of an issue being raised to the University under a specific policy or procedure that may/does not fit with the criteria within, a decision on where best to investigate/deal with the matter is made by the senior staff in charge of the relevant processes. Each policy or procedure articulates, where appropriate, how they may relate or interact with each other.

The current research misconduct procedure does not provide a process for dealing with issues of poor research practice. That is those concerns that were not deliberate or not as serious and therefore should not be investigated via the formal misconduct procedure. Therefore, a revised misconduct procedure has been drafted during 2022-23 and will be approved and implemented in 2023-24 to introduce new methods for dealing with poor research practice issues.

The University will use the opportunity of the new procedure's release to promote the importance of raising research concerns across the research community. This will be promoted alongside other university policies to ensure the continuation and strengthening of an environment where researchers are confident that concerns are heard and investigated appropriately. In addition, where possible, references to the University's misconduct process will also be integrated into the new integrity training provision.

Four research misconduct concerns were raised in 2022-23 (see below table). These were all self-reported issues of non-deliberate breeches of our ethical approval process. It was agreed that no formal investigations needed to take place as all issues were due to misunderstandings. Action was taken in year by the relevant departments to highlight the proper ethics processes to the research community and Lancaster's process will be included in the new ethics training provision to be rolled out in 2023-24.

3B. Information on investigations of research misconduct that have been undertaken. Please complete the table on the number of formal investigations completed during the period under **review** (including investigations which completed during this period but started in a previous academic year). Information from ongoing investigations should not be submitted. An organisation's procedure may include an initial, preliminary, or screening stage to determine whether a formal investigation needs to be completed. These allegations should be included in the first column but only those that proceeded past this stage, to formal investigations, should be included in the second column.

	Number of allegations					
Type of allegation	Number of allegations reported to the organisation	Number of formal investigations	Number upheld in part after formal investigation	Number upheld in full after formal investigation		
Fabrication						
Falsification						
Plagiarism						
Failure to meet legal, ethical and professional obligations	4	0	-	-		
Misrepresentation (eg data; involvement; interests; qualification; and/or publication history)						
Improper dealing with allegations of misconduct						
Multiple areas of concern (when received in a single allegation)						
Other Total:	4	0	_	_		