

# **Research Code of Conduct**



# **Document Control**

Prepared by (lead responsibility)	Shaun Monkman, Ethics and Integrity Manager Richard Thomas, Chair of the University Ethics and Integrity Committee
Approved by	Research and Enterprise Committee
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# **Policy development steps**

ction Description of steps taken	
Legal implications of this policy area	Research undertaken under the auspices of the
	University of Leicester must comply with a
	complex mix of international and domestic
	laws, regulations, principles and expectations.
	This Code sets out how researchers should
	operate and behave to ensure compliance and
	research integrity.
Consultation for this policy	Members of the:
	Research and Enterprise Committee
	University Ethics and Integrity Committee
	Research Integrity Working Group



# **Version History**

Version 1 – 2008	First version of the policy
Version 2 – July 2011	Unknown
Version 3 – October 2014	Unknown
Version 4 – June 2018	Light-touch review including minor revisions
	and updating of references
Version 5 – December 2021	Transfer to new template and separation of
	policy from procedure. Updating of titles for
	committees, departments etc.
	Minor changes to wording for clarification,
	including definition of Research.
	Update to section 8 - Research Misconduct, to
	remove process which is now held within
	Standard Operating Procedures and
	accompanied by updated Guidance for
	Researchers on Research Misconduct
	Updated text in section 5.7 to address changes
	to GDPR legislation.
	Inclusion of details regarding Sensitive, Extreme or Radical Material.
Version 6 – May 2023	Update to facilitate the implementation of
	Infonetica, the new online research
	management platform, around conflict of
	interest.
	Inclusion of reference to the new Financial
	Conflict of Interest Policy (for U.S. Department
	of Health & Human Services and U.S. Public
	Health.

# Related procedures/guidance:

**Research Ethics Policy** 

**Guidance for Researchers on Research Misconduct** 

Standard Operating Procedures for Managing Research Misconduct Investigations

<u>Policy on Researching and Handling Sensitive, Extreme or Radical Material</u>



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## **Policy Text**

# 1. Scope and background

- 1.1.1.The University of Leicester's Research Code of Conduct ('the Code') provides guidelines for good practice in research, and guidance on situations involving misconduct in research.
- 1.1.2.The University is committed to maintaining the highest standards of rigour and integrity in the conduct of its research. The University expects all those involved in research to observe these standards and to embed good practice in all aspects of their work, including the provision of training for new researchers. Good research practice refers to the ways in which research is planned, funded and conducted, results are recorded and reported, and the outcomes of research are disseminated, applied and leveraged.
  - Good research practice will allow ready verification of the quality and integrity of research data, provide a transparent basis for investigating allegations of bad practice or fraud, and lead to better research. The University, its staff, students and collaborators all share in the responsibility for promoting and verifying good practice and creating an ethos of professionalism and integrity in the University's research culture.
- 1.1.3. This Code is intended to provide a clear and public statement of the University's research policies and practices. The Code sets out the obligations on researchers, in all disciplines, to be aware of the policies governing research at the University and to comply with institutional and regulatory requirements. This document should be read in conjunction with the relevant <u>Ordinances and Regulations</u>, and any <u>other policies</u>, procedures or guidance as may be issued by the University from time to time.

## 2. Monitoring and review:

- 2.1.1.The University's Research and Enterprise Committee is responsible for establishing and reviewing policy guidelines for the proper conduct of research, including regularly reviewing and updating this Code to ensure it takes into account current guidelines and relevant legislation. Formal approval of the Code is given by Senate.
- 2.1.2.The University's Research and Enterprise Committee and the University Ethics and Integrity Committee will oversee light-touch reviews of this Code and supporting guidance documents approximately annually to include minor revisions and updating of references. Where the need for more major revisions to all or part of the Code is identified, for example to reflect changes to legislation or changes to funder regulations, the Research and Enterprise Committee will oversee these and seek approval from Senate.



#### 3. Introduction

#### 3.1. Definitions

- 3.1.1.In this Code, the meaning of some words is codified:
  - Where the word **MUST** is in bold, it indicates a **mandatory** requirement for all researchers by the University, or under UK law or other external regulations
  - Where SHOULD is in bold, it indicates a course of action that is recommended as best practice
  - Where MAY is in bold, it indicates a course of action which may be taken at the discretion of the appropriate person or persons
- 3.1.2. For consistency, definitions and meanings of other key words in this Code shall have the same meaning and definition as those found in the University Research Ethics Policy. Those relevant to this policy are detailed below:
- 3.1.3.'Researcher' or 'you' indicates an individual involved in research, including, but not limited to:
  - Staff involved in research from any of the in any of the University's job families including Professional Services, Honorary Staff and Emeritus Professors
  - Staff visiting from other institutions or companies undertaking or supervising research at or for the University
  - Undergraduate and postgraduate students (both taught and research), whether registered here or on temporary placement.

This term also covers those involved in fundraising, providing consultancy, innovation, commercial and analytical services and those involved in the setting up and running of University spin-out companies.

3.1.4. **'Research'** is defined according to the internationally accepted <u>OECD Frascati Manual</u> as "creative and systematic work undertaken in order to increase the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge."

The term Research covers different types of activity including but not limited to basic research, applied research, experimental development and Service Evaluation where the results are likely to lead to shared practices and improvements (i.e. wider dissemination of results beyond the local organisation). Some of the above activities may also be referred to as enterprise activity.

Research is to be distinguished from other types of activity which may not require ethical approval, such as Patient and Public Involvement (PPI) to inform future research, Clinical Audit and Service Evaluation (where the results will be limited to implementation at the local organisation).



- 3.1.5. 'Principal Investigator' or 'PI' refers to the lead investigator generally the main holder of the research funding or leader of a project or, for multi-institution projects, the University of Leicester lead investigator. This definition includes the defined role of Chief Investigator(CI) of a Medical or Clinical Study
- 3.1.6. **'Supervisor'** covers any person responsible for oversight of other researchers.
- 3.1.7. 'Head of Department' refers to the Head of the academic unit to which a researcher belongs. Such units can include Schools, Departments, Research Institutes and other divisions within the University.
- 3.1.8. **'Student'** covers any person who has registered on a programme of study with the University, which can include undergraduate, postgraduate taught and postgraduate research programmes, including those on distance learning courses. This also includes students from elsewhere such as visiting as part of an exchange or similar programme.
- 3.1.9.A 'Research Student' is a student who is registered on a research-based programme of study, such as an MPhil, MRes, professional doctorate or PhD.
- 3.1.10. 'Research Funder' covers any organisation or person which provides research or enterprise funding to the University, and can include research councils, public sector organisations, charities, non-governmental organisations, commercial and business organisations, and government agencies, whether located within the UK or elsewhere. This includes philanthropic donations from private individuals approved by the University governance processes.
- 3.1.11. 'Research Funding' covers all forms of external funding in support of research and enterprise activities including research grants and contracts, philanthropic donations, consultancy and industrial research contracts and grants in kind providing access to external expertise, facilities, equipment etc.
- 3.1.12. **'Clinical Audit'** is designed and conducted to produce information to inform delivery of best clinical care. Designed to answer: "Does this service reach a predetermined standard?". It is always measured against a standard.
- 3.1.13. **'Service Evaluation'** is designed and conducted solely to define or judge current clinical care. Designed to answer a specific question: "What standard does this service achieve?". A Service Evaluation measures a current service without reference to a standard.
- 3.1.14. 'Method/Instrument Validation' is the process used to confirm that the analytical procedure employed for a specific test is suitable for its intended use. Results from validation can be used to judge the quality, reliability and consistency of analytical



results; it is an integral part of any good analytical practice. Where it involves the creation of novel knowledge then it is a form of research.

- 3.1.15. **'Named Person'** is the nominated individual who oversees complaints of Research Misconduct and is responsible for:
  - Receiving any allegations of misconduct in research
  - Initiating and supervising the procedure for investigating allegations of misconduct in research
  - Maintaining the information record during the investigation and subsequently reporting on the investigation with internal contacts and external organisations
  - Taking decisions at key stages of the Procedure.

#### 4. Principles

## 4.1. The Concordat to Support Research Integrity

- 4.1.1.As a supporter of the <u>Concordat to Support Research Integrity</u> the University has made five commitments to strengthen the integrity of our research. We are committed to:
  - Maintaining the highest standards of rigour and integrity in all aspects of research
  - Ensuring that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards
  - Supporting a research environment that is underpinned by a culture of integrity and based on good governance, best practice and support for the development of researchers
  - Using transparent, robust and fair processes to deal with allegations of research misconduct should they arise
  - Working together to strengthen the integrity of research, and reviewing progress regularly and openly
- 4.1.2.Each of the commitments in the Concordat places certain responsibilities upon the Researchers who conduct research for, or at, the University, and upon the University as both an employer and trainer of researchers and as a funder of research.
- 4.1.3. The Code aims to provide clear guidelines to anyone conducting research for, or at, the University, to support researchers in meeting their responsibilities under the Concordat and other ethical, legal and professional standards.

## 4.2. Guiding values and principles

- 4.2.1.Researchers **must** maintain the highest standards of integrity in the conduct of research, guided by the values of honesty, dignity, rigour, transparency and open communication, care and respect, and academic freedom.
- 4.2.2. Research activity **must** be based on the following guiding principles:
  - Research within the University should pursue new knowledge and understanding
  - Research methods and results should be open to scrutiny and debate unless they
    are subject to a contract or similar which requires confidentiality
  - In all aspects of your research you must:
    - o Demonstrate integrity and professionalism



- Ensure the safety, welfare and dignity of those involved in or associated with your research
- Behave ethically and responsibly
- o Ensure the accuracy of your results
- Observe fairness and equity
- o Avoid conflicts of interest and declare them where they exist.
- 4.2.3.Research **must** be conducted with due regard to any legitimate internal or external constraints or procedures which may apply, including legislation, University policies and procedures, and policies and guidance issued by research councils and other organisations. An abridged list of relevant documents may be found in Annex 1.
- 4.2.4. The University expects its members to ensure that their work enhances the reputation and standing of the University and the profession to which they belong, where relevant.

#### 4.3. Observance of the Code

- 4.3.1.Staff in the job families referred to in para 3.1.3 (above) and visiting staff **must** familiarise themselves with this Code and its provisions, and ensure that they and others working around them adhere to these provisions.
- 4.3.2.Staff responsible for teaching or supervising students who are undertaking research **must** ensure that these students are familiar with the core principles of the Code. Researchers will be judged by the standards contained within this Code.
- 4.3.3.In addition to the mandatory requirements indicated by the use of 'must' as defined in para 3.1.1 (above), this Code contains provisions (indicated by 'should') which are recommended as best practice. Whilst these provisions are not mandatory, researchers will normally be expected to follow these recommendations, and researchers who choose not to should do so with good reason and be prepared to account for their actions.

## 4.4. Breach of the Code

- 4.4.1. This Code is linked to, and operates in conjunction with, conditions of employment for the relevant staff groups and other related University policies and procedures. Failure to abide by this Code may lead to the matter being considered under the University's disciplinary procedure.
- 4.4.2. The University may also refer Researchers who fail to comply with the Code to their professional regulatory body (e.g. the General Medical Council) or any relevant authority.
- 4.4.3. For students, matters arising from a breach will be handled in line with <u>Senate</u> Regulation Eleven: Regulations governing student discipline.

# 4.5. Advice and training

4.5.1.If you are in doubt about the applicability of the Code, or about the appropriate course of action to be adopted in relation to it, you must seek advice from a suitable colleague, such as member of the <u>University Ethics and Integrity Committee</u>, a member



- of the relevant <u>Research Ethics Committee</u>, or for NHS-related research, to the Research Ethics, Governance and Integrity Office.
- 4.5.2.Researchers **should** ensure that they take advantage of any training relevant to the Code offered both at a generic level and any subject-specific provision. The University, through its intranet, will draw attention to relevant training.

#### 4.6. External codes

- 4.6.1. This Code has been drawn up to conform with the principles laid out in other relevant policies, guidelines and codes of conduct, including:
  - Universities UK's Concordat to Support Research Integrity,
  - Research Councils UK's Policy and Code of Conduct on the Governance of Good Research Conduct,
  - <u>UK Research Integrity Office's Code of Practice for Research and Procedure for the Investigation of Misconduct in Research</u>
- 4.6.2.In the event of any lack of clarity, this Code should be interpreted in such a way as to conform to the requirements of the documents mentioned in para 4.6.1 (above). Researchers must also adhere to any regulations laid down by their professional body and any legal requirements relating to their research, such as Acts of Parliament or statutory regulations.
- 4.6.3. The University is signed up to the <u>Concordat to Support the Career Development of Researchers</u> and its three overarching principles, of which the following is of particular importance: 'Researchers must ensure they act in accordance with employer and funder policies related to research integrity, and equality, diversity and inclusion'.
- 4.6.4.The University is also a signatory of the San Francisco <u>Declaration on Research</u>
  <u>Assessment (DORA)</u>, which recognises the need to improve the ways in which researchers and the outputs of scholarly research are evaluated. Researchers should be aware of The University Statement of Principles and Guidance <u>for the Responsible</u> use of Bibliometrics.
- 4.6.5.Researchers must have consideration for other external codes or protocols as appropriate, for example the <u>Nagoya Protocol on Access to Genetic Resources</u>.

# 5. Before Starting Research

#### 5.1. Applying for funding and support

- 5.1.1.When you are applying for Research Funding or support of any kind (including grants, fellowships or studentships) you must ensure that the information you provide in any application is clear and accurate.
- 5.1.2. When applying for Research Funding, you **must** familiarise yourself with and adhere to <u>internal and external timelines/deadlines</u>.
- 5.1.3.If you apply for Research Funding or support of any kind, you **must not** seek to identify or approach the assessors of your application. If you are requested to nominate assessors as part of the application process, you **may** approach them to seek their permission to nominate them.



- 5.1.4.When applying for Research Funding, you must make sure that you are familiar with the Research Funder's terms and conditions for applications and awards and ensure that you abide by these at all times. Where application for funding requires formal acceptance of funding terms (e.g. Contract Research), prior discussion with RED must occur to determine that the terms proposed are acceptable.
- 5.1.5.When applying for Research Funding you must comply with University policies and regulations. You must also report to your <u>Research Ethics Committee</u> any application which may give rise to a conflict of interest. More information can be found in section 5.5.
- 5.1.6. Any Researcher who is a signatory on an application for Research Funding or support of any kind **must** share responsibility for ensuring that the information submitted is clear and accurate, and will be held jointly responsible for any plagiarism (including self-plagiarism See 8.2.4), fabrication, falsification or misrepresentation.
- 5.1.7. Where an application involves collaborative working with individuals and organisations outside the University, applicant Researchers **must** ensure the collaborator's costs and any letters of support or agreements are appropriately included in the application.
- 5.1.8. When considering whether to apply for philanthropic funding you **must** seek advice in the first instance from the <u>Development and Alumni Relations Office</u>.
- 5.1.9. The University has an obligation to conduct its fundraising, research and enterprise funding operations and relationships in an ethical manner, and to ensure that due diligence is observed when assessing whether or not to proceed with a funding application, or to accept an unsolicited philanthropic donation or Research Funding, or to establish specific philanthropic relationships or contracts.
- 5.1.10. The University's Research Ethics Policy and Guidelines for the Acceptance and Refusal of Donations and Research and Enterprise Funding provides guidance for staff involved in planning and bidding for philanthropic donations or research or enterprise funding. You must ensure that any Research Funding sought follows these guidelines and, where there is any doubt, you must seek advice from RED in line with the Guidelines for the Acceptance and Refusal of Donations and Research and Enterprise Funding, as appropriate.



## 5.2. Ethics approval procedures

- 5.2.1.All research which requires ethical review, **must** be considered by an appropriately constituted Research Ethics Committee before it begins.
- 5.2.2.The University Research Ethics Policy sets out the scope of ethical review, but for clarity they are repeated here:
  - University ethical review is required for:
    - Research involving human participants, human tissue, material or remains, personal data; and/or
    - Any other types of research that might not involve humans but still raises ethical issues or concerns. For example, the research or results of the research may pose a risk of damage to the environment, cause political or social tensions or sensitivities, or may negatively impact cultural heritage.
  - Animal research ethics is regulated by the <u>University's Policy Statement on</u>
    Research Involving the Use of Animals and applicable statute.
- 5.2.3.Legislation or Government bodies may require ethical review to be conducted by a specific ethics committee. Examples include, the Human Tissue Act, the Mental Capacity Act, or the Medicines for Human Use [Clinical Trials] Regulations 2004 (as amended), the Department of Health's UK Policy Framework for Health and Social Care Research, or where research is funded by the Ministry of Defence.
  - In these cases, ethics review by, for example, the NHS Research Ethics Committee takes precedence over the University ethics system. Researchers should avoid duplication of ethical review.
- 5.2.4. You **must** ensure that ethical approval is acquired prior to an application for Research Funding where this is a requirement of the Research Funder.
- 5.2.5. Ethical approval **will** be required for projects funded by the University and those not receiving any funding at all, as well as for externally-funded projects so long as they meet the definition of Research in section 3.1.4.
- 5.2.6. You **should** seek advice on ethical approvals from the appropriate <u>Departmental Ethics</u> <u>Officer</u> or <u>Research Ethics Committee</u>. Researchers may also seek advice from the <u>Research Ethics, Governance and Integrity Team</u>, in particular around ethics review for research in the NHS.
- 5.2.7. You **must** ensure that ethical approval is secured prior to the commencement of any research where this is required by:
  - Statute or Statutory instrument (such as the Clinical Trials Regulations, Human Tissue Act, Mental Capacity Act or the Animals (Scientific Procedures) Act)
  - Government Policy (e.g. <u>UK Policy Framework for Health and Social Care Research</u>)
  - Regulatory authority, Safety Committee or Professional body
  - Research Funder (e.g. ESRC Framework for Research Ethics or Ministry of Justice)
  - the University Research Ethics Policy
- 5.2.8.Researchers **must** seek ethical approval for activity which meets the definition of Service Evaluation/Clinical Audit (see section 4.2.11/4.2.12) where results are to be more widely disseminated than the local organisation.



- 5.2.9.In the case of laboratory research which involve the use of human samples or data, researchers **must** seek ethical approval. This includes Method/Instrument Validation where the project involves developing a new method or instrument.
- 5.2.10. In cases where ethical approvals are required and external research funding is available, funds will not be released until evidence is received that the necessary ethical approvals are in place. A temporary exemption may be granted for projects in which the development of the methodology forms part of the project such that prior approvals cannot be given.
- 5.2.11. Where ethics approval is required, you must seek ethics review and approval from the appropriate Research Ethics Committee. Researchers are responsible for ensuring that the correct Committee reviews the research. You should contact your Departmental Ethics Officer or Research Ethics Committee for advice on which Committee to approach.
- 5.2.12. If your research involves the NHS it may need <a href="Health Research Authority">Health Research Authority</a> (HRA) approval and review by an NHS Research Ethics Committee. If HRA approval is required, the proposal does not need to be reviewed by a University Research Ethics Committee as well. Visit the <a href="Research Ethics">Research Ethics</a>, <a href="Governance and Integrity">Governance and Integrity</a> webpages for further information.
- 5.2.13. You must seek a favourable opinion (equivalent to approval from other ethics committees) from the relevant NHS Ethics Committee and Health Research Authority (HRA) approval for:
  - Research involving NHS patients (including their tissue or data) or the relatives or carers of NHS patients identified because of this status
  - Health-related research involving prisoners
  - Social care research projects funded by the Department of Health; or
  - Research where ethical review is required by law (e.g. within the remit of the Human Tissue Act, the Mental Capacity Act, or the Medicines for Human Use [Clinical Trials] Regulations 2004, as amended)
- 5.2.14. If a study is using only NHS staff or premises it may not require an NHS ethics opinion but will require HRA approval and will also require review through the University's ethical review system. For advice in this area, you **should** contact the Research Ethics, Governance and Integrity Team.
- 5.2.15. Where the research needs to be reviewed by the University, you **must** submit an application online by using the <u>University Ethics Review</u> system. Policy and Guidance on the University Ethics Review is regulated by the Research Ethics Policy.
- 5.2.16. Where research involves Ministry of Defence funded research, ethical approval **must** be sought from the relevant Ministry of Defence Research Ethics Committee (MODREC).
- 5.2.17. Where the ethical requirements of an approving body conflict with the provisions of this Code, or where the requirements of multiple approving bodies conflict, researchers must seek guidance from the Chair of the <u>University Ethics and Integrity</u> Committee.
- 5.2.18. Research **must** be conducted in compliance with any conditions specified by an approving regulatory body, nominated reviewer, Research Ethics Committee, the



University Ethics Committee or other relevant funder or approving body, and the University's Research Ethics Code of Practice.

# 5.3. Research governance approvals and sponsorship requirements for health research

- 5.3.1.Research where ethical review is required by law (e.g. within the remit of the Human Tissue Act, the Medicines for Human Use [Clinical Trials] Regulations 2004, as amended), or research under the remit of the UK Policy Framework for Health and Social Care Research, may not commence until an appropriate sponsor has been nominated and provides approval for the project to begin. The sponsor is distinct from the funder. Generally, sponsorship is required where research is carried out in the NHS involving NHS patients, their tissue, or data, or involves NHS staff or is carried out on NHS premises, or using NHS facilities or equipment (including GPs providing NHS services).
- 5.3.2.Researchers who wish the University to act as sponsor **must** contact the <u>Research</u> <u>Ethics, Governance and Integrity Team</u> and apply for sponsorship.
- 5.3.3.Clinical and health research which is sponsored by the University must comply with the <a href="Standard Operating Procedures">Standard Operating Procedures</a> approved by the Research Sponsorship Committee.

  The Research Ethics, Governance and Integrity Team can be contacted for advice.
- 5.3.4. Where clinical research is to be undertaken, researchers **must** familiarise themselves with and adhere to the specific roles and responsibilities assigned to them (including the defined role of Chief Investigator of a Medical or Clinical Study) under the relevant legislation, or by other bodies involved with the clinical research.
- 5.3.5. Where the requirements of an approving body conflict with the provisions of this Code, or where the requirements of multiple approving bodies conflict, researchers **must** seek guidance from the <u>Research Ethics</u>, <u>Governance and Integrity Team</u>.
- 5.3.6.Research must be conducted in compliance with any conditions specified by ethical and HRA approval, or other relevant approving body, including the University as Sponsor.

## 5.4. Other approvals

- 5.4.1.Researchers **should** be aware that other aspects of a research project may also require approval or documentation before research commences. Examples include working with biological agents, potentially hazardous chemicals, controlled drugs, chemical weapon precursors, radiation, novel foodstuffs or genetically modified organisms as well as health and safety, data security and information governance considerations. Researchers **must** ensure that all relevant procedures are completed prior to starting. Advice **should** be sought from <u>Health and Safety Services</u>, <u>Information Assurance Services</u>, as appropriate.
- 5.4.2.Additional regulations from the Home Office govern the use of animals in research and all such research **must** be licenced before research commences. The University's <u>Policy Statement on Research Involving the Use of Animals</u> provides more information.
- 5.4.3. Where research involves radical, sensitive or extreme material, including chemicals or organisms that can be used as weapons, Researchers **must** ensure that all procedures



- set out in the University's <u>Policy on Researching and Handling Sensitive</u>, <u>Extreme or Radical Material</u> have been followed and appropriate permissions obtained.
- 5.4.4.Additionally, National Competent Authority approval will also be required for studies using Clinical Trial Investigational Medicinal Products (CTIMP) that fall under the Medicines for Human Use (Clinical Trials) Regulations 2004. In the UK, the competent authority is the <a href="Medicines & Healthcare products Regulatory Agency">Medicines & Healthcare products Regulatory Agency</a>. For further advice please contact the <a href="Research Ethics">Research Ethics</a>, <a href="Governance and Integrity Team">Governance and Integrity Team</a>.
- 5.4.5.It is the Researcher's responsibility to understand any other approvals which are required for the activities they undertake and ensure they are in place prior to the activity starting, examples could include novel foods authorisation, or weapons export approvals.

#### 5.5. Conflict of interest

- 5.5.1.'Conflict of interest' includes any personal or family concern with the outcome of research, or any affiliation or involvement with any organisation sponsoring or providing financial support for a project, or any financial involvement in a project undertaken by a Researcher. To be clear, financial involvement includes direct financial interest, provision of benefits (such as travel and accommodation) and provision of material or facilities.
- 5.5.2. You **must** make **full** disclosure of any conflict of interest associated with or arising from your research to the approving <u>Research Ethics Committee</u> as soon as reasonably practicable and identify the nature of the conflict by submitting an amendment to your application form or when completing a reporting form. Where conflicts are identified at the time of applying for ethical review these **must** be declared on the form.
- 5.5.3. You **must** comply with any instructions, requirements or directives from your approving Research Ethics Committee in relation to a conflict of interest in research.
- 5.5.4.The University's Financial Regulations provide guidance on acceptance of gifts and other financial matters.
- 5.5.5.Where the Unites States Public Health Service is the funder the researchers must ensure compliance with the <u>Financial Conflict of Interest Policy</u> (for U.S. <u>Department of Health & Human Services and U.S. Public Health</u>.

## 5.6. Working with individuals and organisations outside the University

- 5.6.1. Formal agreements **must** be in place before research commences, where research is conducted in partnership with individuals or organisations outside of the University and agreement needs to be documented regarding topics such as:
  - Publication and authorship;
  - Ownership of intellectual property;
  - The responsibilities of researchers;
  - Financial liabilities;
  - Indemnity;
  - Data ownership;
  - Procedures for the resolution of issues and the investigation of allegations of misconduct.



- Depending on the nature of the project, agreements may also include arrangements for data sharing, supply of drugs, chemical or other materials and other project-specific issues.
- 5.6.2.All philanthropic support for research projects or programmes **must** be the subject of a Gift Agreement and the PI **must** work with the Philanthropy, Alumni and Community Engagement Team in producing such documents for approval.
- 5.6.3. The PI must ensure that the Research and Enterprise Division (RED) is informed and RED will negotiate agreements with the relevant individuals and organisations. You must not sign any research-related agreements (including, but not limited to, consultancy, research grants, materials transfer and confidentiality / non-disclosure agreements) without specific approval from RED.
- 5.6.4.If a project may result in exploitable intellectual property and any revenue sharing should the intellectual property be commercialised, you **must** contact RED for advice, as outlined in the University's <u>Policy for the Treatment and Governance of Intellectual Property</u>
- 5.6.5. You **must** consider any issues that might arise relating to intellectual property at the earliest opportunity, and ensure agreement is reached in advance on how they will be addressed.
- 5.6.6.Researchers **must** familiarise themselves with and adhere to the standards and procedures for the conduct of research laid out in any related agreement. You **should** pay particular attention to projects involving collaborators from different countries or work carried out in another country and be aware of any additional legal and ethical requirements or other guidelines which may apply as a result. The OECD report Opportunities, Challenges and Good Practices in International Research Cooperation between Developed and Developing Countries contains useful guidance in this area as do Doing Global Science: A guide to responsible conduct in the Global Research Enterprise from the Inter-academy Partnership and the European Code of Conduct for Research Integrity from ALLEA.
- 5.6.7.Researchers **must not** enter into any agreement that may be overridden by the Freedom of Information Act. Researchers **should** be aware that the University is considered a 'public authority' subject to the Freedom of Information Act, and thus information held by the University, including research data, may be subject to freedom of information (FOI) requests. You **must** contact <u>Information Assurance Services</u> for queries relating to FOI and RED for contracts, so they can negotiate any confidentiality, non-disclosure or similar agreements.

# 5.7. Preparations for research data collection

5.7.1.Many Research Funders require a data management or data sharing plan as part of a grant application. You must consider, at an early stage in the design of your project, and propose to your funder, how you will manage and share your data. You need to consider methodologies for data collection, managing and storing your data, data security, data access and data sharing post-project. The Classification of Data must be considered using the <u>University model</u> which will highlight associated data handling issues, requirements and appropriate IT. Appropriate technical and organisational



measures to implement the data protection principles and to safeguard data **must** be put into place both when the means of processing is decided, and at the time of the processing itself. Data security measures **must** be built into the design throughout the lifecycle of the data. Appropriate measures may include pseudonymisation. Privacy by design and default (i.e. inclusion of privacy and data protection compliance from the start of the project) is a mandatory requirement, and ignoring this can lead to a fine. The Data Protection Act 2018 creates a new criminal offence for a person knowingly or recklessly re-identify information that is personal data without the consent of the controller responsible for de-identifying the personal data.

- 5.7.2.The General Data Protection Regulation (UK GDPR) and Data Protection Act 2018 both came into force on 25th May 2018 and apply together. UK GDPR significantly enhances the rights of individuals, and places greater responsibilities on organisations that manage personal data. For Researchers, due regard will need to be given to obtaining and recording consent, building privacy by design and default into the research process at the very start, and carrying out a privacy impact assessment. Advice can be obtained from Information Assurance Services (IAS) and the IAS web pages. The Information Commissioner's Office, which is the Supervisory Authority for the UK, publishes useful guidance.
- 5.7.3.As part of UK GDPR obligations, before processing the personal data of research participants, a legal basis for that processing **must** be identified and recorded along with the purposes of processing. In addition, a description of the categories of the following also needs to be maintained in an Information Asset Register held by the University: data subjects; personal data; and recipients to whom the personal data will be disclosed. Please note that 'Legitimate Interests' as a legal basis will only be available to use in limited circumstances. Contact IAS for further information and any additional requirements to which you may be subject.
- 5.7.4. For Universities in England, the UK GDPR 'Article 6' legal basis for the processing of personal data will normally be a 'task in the public interest'. If consent is used as the legal basis, it **must** be freely given, specific and informed and **must** include an unambiguous indication of an individual's wishes. Consent to the processing of personal data (as defined in UK GDPR) **must** be 'explicit', which means consent in writing or its electronic equivalent. This consent may be separate from consent to take part in the research project. Researchers **must** remember that participants have the right to refuse or withdraw consent at any time for any reason. Consent **must** be properly recorded, as **must** withdrawal of consent, with evidence maintained for both.
- 5.7.5.Consent must be structured so that participants opt in to research activities rather than opt out. It is acceptable for some activities to be optional.
- 5.7.6. Where processing operations involving identifiable personal data are likely to result in a high risk to the rights and freedoms of participants, researchers are required (via OneTrust software with support from IAS and from the local divisional or college Data Champions) to carry out a Data Protection Impact Assessments to evaluate, any risks. The outcome of the assessment **should** be taken into account when determining the appropriate contractual and security measures to be applied to ensure that the processing of personal data complies with data protection legislation. Where the



- assessment indicates a high risk which the University cannot mitigate by appropriate measures in terms of available technology and costs of implementation, the Data Protection Officer will consult with the Information Commissioners Office (ICO) and data processing **must not** begin unless and until IAS approval has been issued.
- 5.7.7.IT Services, Information Assurance Services (IAS) or, in relation to NHS and patient data, the Information Governance Lead and Research Ethics, Governance and Integrity Team can provide advice on information and data security, including the storage, backup, and secure transfer of research data and encryption of sensitive or confidential information.
- 5.7.8. More information on research data management can be found in sections 6.3, Managing research data and 7.4, Providing open access to research outputs. You **should** also consult the Data Management guidance (is there a link to add?) on the University website.

#### 5.8. Arrangements for supervision of research

- 5.8.1.Heads of Department or School **must** ensure that specific, responsible and appropriately qualified researchers are assigned to act as supervisors for each student undertaking research (including at undergraduate, Master's and doctoral levels), trainee researcher (such as clinical trainees) or research assistant within their academic unit.
- 5.8.2.Heads of Department or School **must** monitor the number of students, research assistants and trainee researchers assigned to a particular supervisor to ensure effective intellectual interaction and effective oversight of the research at all times. Heads of Department or School **must** ensure that the <u>Senate regulation</u> concerning the number of research students being supervised, and the status of the supervisor, are adhered to.
- 5.8.3. Supervisors **must** familiarise themselves with their responsibilities as set out in this Code. Supervisors **must** observe all the responsibilities set out in the Code and **must not** accept appointment as a Supervisor if they do not expect to be able to discharge all of these responsibilities. See section 6.7, Responsibilities of supervisors for further details.
- 5.8.4. Supervisors **must** also ensure that they are aware of, and abide by, <u>Senate Regulation</u> 9, which governs research degree programmes.
- 5.8.5.The Head of Department, School, College, or Supervisor, should provide each student undertaking research or trainee researcher or research assistant with written material on applicable government and institutional guidelines for research conduct, including this Code and other policies, codes of practice and guidelines on research integrity, ethical requirements for studies on humans and animals (where appropriate), confidentiality and occupational health and safety.
- 5.8.6.Recruitment of researchers **must** be carried out in accordance with the University's equal opportunity policy and recognised recruitment processes for staff or students, as appropriate.

#### 6. During the Research Project



#### 6.1. Confidential Information

6.1.1. Supervisors **must** ensure that they and any students or other researchers under their supervision comply with all the provisions of agreements prepared by the Research and Enterprise Division. This includes all confidentiality provisions, which are very likely to extend beyond the term of the contract. The Research and Enterprise Division can advise on compliance with contractual provisions.

## 6.2. Intellectual property

- 6.2.1. In line with UK legislation, the University owns all intellectual property or other materials developed by its employees, unless explicitly stated otherwise. In exchange, the University provides generous revenue sharing schemes for employees and their Departments, should the intellectual property be commercialised. Details of the schemes can be found in the Policy for the Treatment and Governance of Intellectual Property. The University does, however, waive copyright of academic outputs such as theses, journal articles, books or book chapters.
- 6.2.2. Students are not employees of the University and therefore legally own any intellectual property arising from their research as long as all of the creative intellectual input has been that of the student. Where the research results clearly arise out of the intellectual input from both the student and supervisor then, depending on the particular circumstances, the intellectual input is jointly owned by the student and the University or each owns any intellectual property that results from their respective creative inputs, subject to the individual circumstances of each research activity.
- 6.2.3.When a researcher is both a student and an employee (e.g. a graduate teaching or research assistant, an undergraduate doing hourly paid work via Unitemps, or a member of staff taking a part-time undergraduate, postgraduate taught or postgraduate research degree), ownership of intellectual property will normally be determined by whether the intellectual property was created during the researcher's duties as a member of staff or a student.
- 6.2.4.The University will decide, on a case-by-case basis, whether students should assign their intellectual property to the University. Supervisors are responsible for ensuring that the appropriate documentation for executing such an assignment is signed in conjunction with the Research and Enterprise Division. On assigning their intellectual property to the University, students will benefit from the University's <a href="Policy for the Treatment and Governance of Intellectual Property">Policy for the Treatment and Governance of Intellectual Property</a> the same terms as employees.
- 6.2.5. Where funding (cash or in kind) is received from an external body, there may be agreement that the sponsoring body has rights to ownership of intellectual property arising from the project. The supervisors of students involved in such a project, in conjunction with the Research and Enterprise Division, are responsible for ensuring that the appropriate assignments of ownership are in place between any student and the University.
- 6.2.6. The University's Policy for the Treatment and Governance of Intellectual Property sets out the procedures to be followed **should** you make an invention or discovery in the course of a research project carried out as part of your normal University activities. It is essential that you contact the Research and Enterprise Division at an early stage to



- obtain advice and guidance. You **must** also be aware of the need to maintain confidentiality regarding the results of research, pending legal protection, in accordance with any instructions or advice from the Research and Enterprise Division.
- 6.2.7.There is a range of ways in which confidentiality can be compromised by disclosure of information including a discovery or invention. Disclosures may occur as a result of posters, presentations, emails, informal conversations etc., in addition to published work. Breaches of confidentiality may result in actions for recovery of losses by a Research Funder or external collaborator against the University and the individual concerned, together with a loss of income. Even if a funder is not involved, breaking confidentiality will result in an inability to protect the relevant intellectual property at any time in the future. It is possible to have confidential conversations without compromising IP under the protection of a confidentiality agreement; such agreements can be prepared by the Research and Enterprise Division, to which all enquiries should be directed.
- 6.2.8.If you leave the University, any intellectual property developed during your employment which is owned by the University, or by any funder to whom such intellectual property has been assigned in accordance with a relevant contract or licence, remains the property of the University or funder. It must not be divulged to third parties without the permission of its owner, unless it is already in the public domain.
- 6.2.9. Where activity involves collaborative working with individuals and organisations outside the University, any protectable intellectual property developed by collaborators will be handled as agreed in the contract. If the confidentiality clause of the contract contains suitable provisions, details of the intellectual property may be disclosed to all of the collaborators; otherwise it will be necessary to keep the details to those deemed 'inventors' only.
- 6.2.10. Researchers **must** ensure that they do not divulge information received from a third party under terms of confidentiality (even to other University employees unless explicitly permitted) without written permission, as to do so may render them liable to claims by the owner of the information. Such restrictions are very likely to persist beyond the end of a project.



#### 6.3. Managing research data

- 6.3.1. The University regards research data as a valuable asset. The management of research data is an integral part of good research practice that allows reliable verification of results, protects the intellectual and financial investment made in its creation, enables it to be shared, and prompts new and innovative research.
- 6.3.2. You **must** apply the <u>University's Research Data Management Principles</u> in managing your research data.
- 6.3.3.Research data must be recorded legibly, clearly and accurately in a suitable form, with appropriate references. A series of general and funder-based data management guides and a <u>dedicated University website</u> are available. NHS-related data must be recorded in line with any source data agreements, data management plans and rules relating to recording of data in medical notes etc.
- 6.3.4.Records created in the course of research must be retained in accordance with University of Leicester <u>records retention schedules</u>. A flow chart documenting the possible retention periods for research data can be found <u>here</u>.
- 6.3.5.Backup copies of electronic data **should** always be made and retained, and files **should** preferably be held in a data archive. Information that is held on central facilities managed by IT Services are regularly backed up, including all files and emails held within University IT accounts (including R: or Research Filestore which is the default location for research data X: and Z: drives, but not local drives).
- 6.3.6.Researchers **should** ensure that they have plans in places for appropriate short-term data storage, creation of metadata, access control, sharing, secure data transfers, data back-up and long-term curation including selection and use of long-term storage via a repository or archive and the use of suitable formats, as outlined in the Research Data Management Principles.
- 6.3.7. When undertaking sensitive, security or terrorism-related research, researchers **must** ensure that they have suitable encryption and storage systems in place before research commences.
- 6.3.8.You **must** handle all research data, associated documentation or information and communications, in whatever format, in compliance with the <u>Information Security Policy</u>. Guidance can be obtained from IT Services and from Information Assurance Services. Risk assessments **must** be carried out where appropriate.
- 6.3.9.Researchers must report immediately to IAS any loss of security or data breach likely to result in some degree of risk to the rights or freedoms of participants. A personal data breach is defined as a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. All systems breaches must e reported to IT Services. Any loss of security is likely to qualify as a personal data breach. The University (via IAS) is required to notify some breaches to the Office of the Information Commissioner within 72 hours of having become aware of it.
- 6.3.10. Where data are supplied by a third party, advice on contractual matters **must** be sought from Purchasing, IT Services and Information Assurance Services in addition to any advice from the Research and Enterprise Division.



#### 6.4. Use of Personal Data

- 6.4.1. 'Personal data' means any recorded information, relating to an identified or identifiable person ('data subject'); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier, Internet Protocol (IP) address, or to one or more factors specific to their physical, physiological, genetic, mental, economic, cultural or social identity.
- 6.4.2.Where research involves the processing of identifiable personal data Researchers **must** ensure that the research activity is documented and included in the University's Records of Processing Activities (ROPA) which is a mandatory requirement under data protection legislation. In most cases this information will either be captured via the University's ethics approval process or as part of the NHS sponsorship process. To confirm whether your research needs to be, or is, captured in the ROPA contact Records Management. The ROPA questions also represent a threshold DPIA (described at 5.7.6), which is the preliminary risk assessment to identify risks to the rights and freedoms of individuals whose personal data is being processed. Therefore, prompt completion of the ROPA allows multiple compliance actions to be completed.
- 6.4.3. You **must** ensure that any use of data within your research complies with the General Data Protection Regulation and the Data Protection Act 2018. Special care **must** be taken with personal data, which **must** be processed in accordance with the applicable legislation and the University's Data Protection Policies, and **must not** be kept longer than is necessary for that purpose. Researchers **must** pay particular attention to the Data Protection Policies with respect to the collection, processing, protection, retention and disposal of personal data.
- 6.4.4. Researchers **should**, wherever practicable, use anonymised data for research. You **should** remove or destroy any personal identifiers from non-anonymised data received unless it is absolutely necessary to retain them for research purposes.

# 6.5. Freedom of Information and Data Protection requests

- 6.5.1.Researchers **must** immediately refer any requests for information through the Freedom of Information Act or, for access to personal data through the Data Protection Act 2018 or the General Data Protection Regulation, to Information Assurance Services. You **must not** respond to any requests yourself.
- 6.5.2.Researchers **must** be aware that research data may be accessible through the Freedom of Information Act, although exemptions do apply.
- 6.5.3.Researchers **must** be aware that under data protection legislation individuals have a statutory right to obtain a copy of personal data held about them, although exemptions do apply and you should make yourself aware of them. All such requests **must** be forwarded to Information Assurance Services without delay.

#### 6.6. Use of research funds

6.6.1.If you are in receipt of external Research Funding you must notify RED and obtain approval of University acceptance of the funder terms and conditions.



- 6.6.2.If you are in receipt of Research Funding, you **must** use those funds for the purpose for which they were provided and in accordance with the conditions for accepting those funds. You **must** familiarise yourself and others involved with the research with those conditions in order to ensure they are not accidentally breached.
- 6.6.3. If you hold Research Funding you **must** ensure that you do not, either by action or inaction, prevent the University from fulfilling its obligations to the Research Funder. Researchers **may** contact the Research and Enterprise Division at any time during or beyond the end of a research project for further information.
- 6.6.4.Before any change is made to the research project (including the use of funds, scope of project, duration, staff, deliverables) RED must be consulted for advice. Where required written consent **must** be obtained from the Research Funder.
- 6.6.5. Researchers who hold Research Funding **must** assist the University in compliance with the monitoring and audit requirements of the Research Funder. Principal Investigators **must** ensure that all researchers involved with a research project are aware of their responsibilities in this area.
- 6.6.6. You **must** comply with all University and Research Funder regulations relating to the employment of staff using Research Funding.

## 6.7. Responsibilities of supervisors (including managers of research staff)

- 6.7.1.Supervisors must provide any researchers they are supervising with guidance on all matters of good research practice. This includes discussing, at the outset, relevant issues of intellectual property, research conduct and ethics with research students, research assistants and trainee researchers, and referring any problems or queries to the Head of Department or School.
- 6.7.2. Supervisors **must** ensure that staff researchers:
  - have access to annual appraisal and are encouraged to take part in this;
  - are able to request flexible working especially for family and caring responsibilities;
  - have working arrangements that do not directly discriminate against groups associated with a protected characteristic nor indirectly discriminate unless it cannot be avoided and is justifiable;
  - have access to mentoring or training organised on a Departmental, School or College basis or centrally, and are encouraged to attend relevant opportunities;
  - have access to facilitated maternity, adoption or paternity leave (supervisors should seek permission to cover the costs from research funders or, failing that, from the University).

More information on equal opportunities can be obtained from the Equality, Diversity and Inclusion Team.

- 6.7.3. The policy on pregnancy, maternity, paternity and adoption provides guidance for postgraduate research students who are pregnant or become parents at the commencement of or during their studies.
- 6.7.4. Supervisors **must** ensure, as far as possible, the validity of research data obtained by researchers under their supervision.



- 6.7.5. Where a student is processing personal data as part of their studies, supervisors **must** ensure that the processing complies with the Data Protection Act 2018, the General Data Protection Regulation and any other applicable legislation.
- 6.7.6. Supervisors **must** ensure that students and other researchers under their supervision are made aware of any training provided on good conduct in research, and **should** ensure attendance at mandatory courses, as well as encouraging attendance at other relevant courses.
- 6.7.7.The supervisors of research students (such as those registered for MPhil, MRes, PhD or a professional doctorate) have a particular responsibility to ensure appropriate recognition of the student's contribution to any research on which a publication in based. An agreement, preferably written, **should** be reached early in the candidature between the supervisor and the student in respect of the attribution of authorship, embracing the principles of open and mutual recognition. Supervisors **must** also ensure that they are aware of, and abide by, the Senate regulation covering research degree programmes.
- 6.7.8. Supervisors **must** ensure that ethical approval is obtained by students, where required, for any research undertaken by staff and undergraduate or postgraduate students working under their supervision.

#### 7. After Research

## 7.1. Publishing research outputs

- 7.1.1.Researchers must publish and disseminate research in a manner that reports the research and their findings accurately and without selection that could be misleading. If the terms of funding require publication within a set period, researchers must make every effort to meet these deadlines, for example the 12-month deadline set for clinical trials under Good Clinical Practice rules.
- 7.1.2.The University and research funders regard Open Access (OA) to research outputs as being integral to research excellence and the sharing and creation of new knowledge. The University Open Access Policy outlines the routes to achieve Open Access.
- 7.1.3. Anyone who has participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research must be given the opportunity to be included as an author of a publication derived from that research (see also section 7.2, Authorship and acknowledgment).
- 7.1.4. Any person who has not participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research **must not** be included as an author of a publication derived from that research.
- 7.1.5. Where the publication or dissemination of research or research findings generates, or may generate, interest from the media or the general public, researchers **must** seek advice from the Press Office.
- 7.1.6.A publication must contain appropriate reference to the contributions made by all participants in the research, and information on sources of financial support for the research upon which the publication is based. Authors must seek permission to include such references, and agreement on the specific form of words to be used, prior to publication.



- 7.1.7. Where a Research Funder or contributor specifies a form of words and/or content for acknowledgements of support or protection of anonymity, you **must** make sure that your reference meets these requirements.
- 7.1.8.If you are put under pressure, by sponsors and Research Funders or other parties, to discourage or suppress appropriate publication or dissemination, or to influence the presentation or interpretation of findings, you **must** report this to the Named Person in the first instance.
- 7.1.9. Any publication from Research that falls within the scope of a formal agreement must adhere to the requirements set out in that contract.
- 7.1.10. Each author of a publication **must** agree to its final, published, version.
- 7.1.11. All authors share responsibility for the veracity of the published work. Each author must satisfy themselves that the research reported has been carried out properly and ethically.
- 7.1.12. A publication that is closely related to another publication derived from the same research (such as one using the same dataset) must contain appropriate reference to the other publication.
- 7.1.13. You **must not** submit work that is substantially similar in style or content to more than one journal or publisher unless it has been rejected by the previous journal or publisher. You **must not** re-use (substantial parts of) work that has been previously published without seeking permission from the copyright holder (e.g. republishing journal articles as book chapters at a later date).
- 7.1.14. The bibliography for a publication **must** be appropriate for the output, accurate and avoid excessive self-citation.
- 7.1.15. Forthcoming publications **must** be accurately described in references and lists of publications, using terms such as 'in preparation', 'submitted to', 'accepted for publication', 'forthcoming' or 'in press', and subject to the rules of publishers and journals.
- 7.1.16. If a published work be found to contain errors, other than those of a minor, typographical nature, the editor of the journal or the publisher **must** be informed immediately. The appropriate corrective action, for example through publication of a correction or retraction of the paper, **must** be determined in consultation with the editor. The action **must** be reported to the Named Person who will consider whether the error arises from misconduct in research and whether further action is needed.
- 7.1.17. Although the University does not assert its ownership of the copyright in respect of material such as books, journals and articles, it does retain its right to use and produce such materials for internal educational purposes whilst recognising the author's moral rights.
- 7.1.18. You **must** ensure that all reports and other publications arising from research projects bear an appropriate assertion of copyright.
- 7.1.19. You **must** ensure that the addresses of all University-affiliated authors are stated in the publication in a format that complies with the University policy on <u>Institutional Affiliation in Research Publications</u>, to ensure that the University receives the appropriate academic prestige and acknowledgement in citations of the publication.



- 7.1.20. Any conflicts of interest **must** be declared when research findings are reported at meetings, conferences, in presentations or in publications.
- 7.1.21. Researchers **should** seek advice from the Research Ethics, Governance, and Integrity Team or a Research Ethics Committee, as appropriate, in cases where the publication and dissemination of research and the findings of research includes:
  - Confidential or proprietary information;
  - Information or data relating to patents or intellectual property;
  - Findings with serious implications for public health; and/or
  - Contractual or legal obligations.

# 7.2. Authorship and acknowledgement

- 7.2.1. Any person who is to be included as author of a publication must
  - Have made a substantial contribution to the research from which the publication is derived;
  - Be familiar with the entire contents of the publication;
  - Have participated sufficiently in the research to take public responsibility for the content of the publication; and
  - Meet any criteria for authorship made by a publisher or editor.
- 7.2.2. Any person who does not meet the criteria in para 7.2.1 of this Code **must not** be included as author.
- 7.2.3.It is good practice to utilise the CRediT Contributor Roles Taxonomy scheme when preparing publications, even where not required by a publisher.
- 7.2.4. Any person or organisation who has made a contribution to the research, but who does not meet the criteria in para 7.2.1 of this Code to be included as author, **must** be formally acknowledged in a publication based on that research. Individuals, such as respondents or patients, may be acknowledged as a group rather than individually.
- 7.2.5.Where a researcher believes that they have been unfairly denied the opportunity to be included as an author of a publication, or that they or another researcher has been incorrectly included as an author, the involved parties **should** first seek to reach agreement amongst themselves. If this is not possible, researchers **should** seek assistance from the Named Person.
- 7.2.6.Guidance on publication and authorship is provided by the <u>Committee of Publication</u>
  <u>Ethics</u> (COPE) and the <u>International Committee of Medical Journal Editors</u>. You may also find the UKRIO guidance note <u>Good practice in research: Authorship</u> useful.
- 7.2.7. Where Artificial Intelligence, Machine Learning or Large Language Models are used this must be explicitly stated on the output

## 7.3. Providing open access to research outputs

- 7.3.1.The University has an Open Access Policy requiring free unrestricted online access to all published research outputs authored by members of the University, where allowed by agreement with the publisher. Authors **must** follow this policy, seeking advice from the Library Open Access team where needed.
- 7.3.2.Staff authors **must** submit the full text of their accepted manuscript (in the case of journal articles and conference proceedings) to the <u>Figshare Leicester Research Archive</u>



- (LRA) via the <u>Integrated Research Information System</u> (IRIS) within 3 months from date of acceptance for publication. The bibliographic details of these and also all other publications **should** be included in IRIS. In some cases, the LRA may accept the final published version of a publication (Version of Record) where this is permitted by the publisher. Manuscripts are made publicly available from the LRA after the expiry of any publisher embargo period which may apply.
- 7.3.3.Where a publication reports the results of research which has been partly or fully funded by an external source, the authors **must** ensure that they comply with each research funder's open access requirements, as stated in the research funder's terms and conditions of funding. Open access deposit is now mandatory for work supported by many funders and for journal articles and conference proceedings that might be submitted to the <u>Research Excellence Framework</u>. Authors **should** seek advice from the <u>Library Open Access team</u> if in any doubt.
- 7.3.4. Where a research funder has awarded an open access block grant to the University to cover GOLD open access publication costs an application to secure the funds from the open access block grant **must** be made to the Library open access team before the output is submitted for publication.
- 7.3.5. Where there are no research funds to pay for GOLD open access publishing the GREEN open access route (no charge to the author) is the University's preferred route for open access, as outlined in the University Open Access Policy.
- 7.3.6.Student authors **should** approach the Library's open access team for assistance on depositing publications in the <u>Figshare Leicester Research Archive</u> by contacting openaccess@le.ac.uk.
- 7.3.7.Doctoral students are required to make an electronic copy of their thesis available as open access. They must deposit an electronic copy of the final thesis in the Figshar Leicester Research Archive in accordance with the instructions in the Student Handbook. Students should familiarise themselves with the allowances for embargo periods, as set out in the Handbook, and ensure that they make any request for an embargo at the appropriate time.

## 7.4. Providing open access to research data

- 7.4.1.Researchers **should** make publicly funded research data openly available, with as few restrictions as possible, in a timely and responsible manner that does not harm intellectual property or research participants, in line with the policies of any research funder.
- 7.4.2.Research data related to publications **should** be made available for consultation by researchers outside the group which conducted the initial research, except where confidentiality provisions prevail.
- 7.4.3. For all NHS-related research, researchers are encouraged to deposit suitably formatted data in a publicly accessible database: this is mandatory for all clinical trials involving an investigational medicinal product (drug studies).
- 7.4.4. Where required by a publisher or funding body, you **must** deposit your research data in either an external subject-specific repository or the <u>Figshare Leicester Research</u>



- <u>Archive</u>. Before submission researchers must ensure that there are no contractual or other issues with the release of the data. Refer to 7.1.20.
- 7.4.5.Confidentiality provisions may apply in circumstances where the University or the Researcher has made or given confidentiality undertakings to third parties, or confidentiality is required to protect intellectual property rights. You **must** be aware whether confidentiality provisions apply and, if you are the Principal Investigator, ensure that all other researchers on the project are aware of these obligations. Advice on confidentiality agreements with potential commercial or industrial exploitation partners to protect intellectual property rights, including any embargo periods on publications, may be obtained from Research and Enterprise Division.

## 7.5. Retaining records and research data

- 7.5.1.Long-term storage and access to preserved research data **should** be managed through either an appropriate funder-provided, discipline-specific facility or the University of Leicester <u>Figshare Leicester Research Archive</u>. You **should**, wherever possible, store primary and secondary research data in a secure and accessible form. Research data resulting from a study **should** be available to other researchers under FAIR principles (Findable, Accessible, Interoperable and Re-usable), so that they may replicate the study or elaborate on its findings.
- 7.5.2.Confidential information (including personal data) **must** be destroyed and disposed of securely once it is no longer required, after agreed periods of retention have expired, or in cases where destruction is required for legal or ethical reasons, in accordance with the University's Records Retention Schedules. Sensitive paper documents **should** be shredded, and electronic data **should** be securely erased. You **should** seek assistance from your <u>Data Champions</u> or IT Services for advice on the secure disposal of electronic data. In addition, you **must** ensure that you comply with any additional legal or ethical requirements, or requirements from research funders or collaborating organisations, regarding the secure disposal of confidential data.
- 7.5.3.For data and documents related to clinical trials, Researchers must be aware of the University's responsibilities as a sponsor of clinical trials, and ensure that they retain the essential documents required by the Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 or any subsequent regulations. Standard Operating Procedures for studies which are sponsored by the University must be followed. Further information, including details of the essential documents, can be found in the Standard Operating Procedures of the Research Sponsorship and Management Group.
- 7.5.4. Data **must** be retained intact for a period in line with the University's <u>Research Records Retention Flowchart</u>, or any longer period required by an approving body, the research funder or under legislation. Minimum periods commence on the date at which the final report was sent to the research funder or the date on which the output was published or, for student research, the date of submission of the thesis or dissertation. The term 'data' here includes all unpublished evidence, whether numerical or otherwise, on which the publication is based and from which results can be replicated or reproduced. Hard copy, such as laboratory notes, field notes, questionnaire responses, signed



- consent forms, the research protocol for the project, photographic records, and subsequent electronic files **should** all be retained.
- 7.5.5.Researchers **should** be aware that the retention periods may vary, in line with regulatory requirements, and **should** ensure that they are aware of any changes to data retention regulations, and abide by them. Further information and advice on retention periods can be obtained by contacting the University Records Manager.
- 7.5.6.Research Ethics Committees, funders or approving bodies may, for an individual project, extend the length of retention period or redefine the minimum data that should be retained if they consider it appropriate. Researchers must ensure that they abide by the retention requirements of any relevant bodies and any project-specific variations.

## 7.6. Acting as a peer reviewer for funding applications

- 7.6.1. The assessment procedures used by the Research Councils, major charities, and Government Departments are based extensively on peer and merit review, combining as necessary the views of expert referees and of committees or panels, whose members have been drawn from the academic and other user communities.
- 7.6.2.Individuals agreeing to contribute to the peer review process for external organisations, including those providing Research Funding must observe the following rules:
  - All the information made available to a Researcher as a peer reviewer **must** be treated in the strictest confidence.
  - Peer review must be undertaken in accordance with any rules, guidance or regulations of the body making the request.
  - Reviewers must not take advantage of any information obtained as a result of their role; in particular they must not pirate unfunded proposals.
  - Reviewers must declare any conflicts of interest and, normally, decline an
    invitation to review, or withdraw from the relevant discussion(s). Anyone with
    close professional, personal or commercial interest in a piece of work, or a
    member of the same University Department as the applicant(s), is ineligible to
    comment.
  - If reviewers consider themselves to be insufficiently expert in the area of research on which they have been asked to comment, they **must** make this clear; in such circumstances, they **should** return the work they have been asked to judge.
  - If reviewers are unable to respond to the request within the timescale indicated, they **should** immediately inform the person or organisation making the request and agree whether an extension is possible or if they **should** decline the request.
- 7.6.3.If the peer review rules/guidance provided by the research funder or other external body making the request is in conflict with the rules in para 7.6.2 (above), the rules/guidance provided by the research funder or other external organisation may takes precedence if it would make the peer review more robust.
- 7.6.4. Any staff asked to peer-review internally, such as during the development of applications for Research Funding, **must** consider themselves bound by the above guidance, with the exception that members of the same University Department as the



applicant are not barred from providing internal review. However, it is recommended that some reviewers come from different Departments to the applicant.

## 7.7. Reviewing manuscripts and other confidential information

- 7.7.1.The provisions above on peer review of grant proposals apply equally to the review of manuscripts for publication and all other forms of confidential information received (for example, in respect to patents, technical or commercial reports etc.). The term 'manuscript' used in this section refers to all and any such forms of confidential information.
- 7.7.2. Reviewers of manuscripts **must** adhere to the guidelines of the publisher/originating body and **must** treat manuscripts in the strictest confidence even when the requirement is not explicit in the publisher's/originator's guidelines.
- 7.7.3. Where sight of a manuscript is likely to lead to a conflict of interest because it contains information and/or conclusions which are similar to those being brought to press (in a journal, book, patent or any other form of output) by the reviewer, whether collaboratively or otherwise, the manuscript must not be reviewed and must be returned to the publisher/originator immediately.
- 7.7.4. This section also applies to internal reviewing of draft outputs for colleagues and any assessment of unpublished outputs for the <u>Outputs Quality Review Policy</u>, Research Excellence Framework or similar exercises.



#### 8. Research Misconduct

## 8.1. Misconduct Policy

- 8.1.1.The University considers misconduct in research to be completely unacceptable. All Researchers **must** adhere to the principles of good practice outlined in this Code, in addition to any additional requirements placed upon them by legislation, professional bodies or other organisations. These additional requirements include, for example, those relating to projects requiring research sponsorship.
- 8.1.2. Alleged research misconduct by University staff will be dealt with according to <a href="Ordinance 23">Ordinance 23</a> (Discipline) and its associated Policy and Procedure. Alleged research misconduct involving investigators holding current or recent Research Funding will be reported in accordance with Research Funders guidance.
- 8.1.3. Cases of alleged misconduct involving registered students (both undergraduate and postgraduate) will be dealt with according to the procedures laid out in the relevant student regulations.
- 8.1.4.When a researcher is both a student and an employee (e.g. a graduate teaching or research assistant, an undergraduate doing hourly paid work via Unitemps, or a member of staff taking a part-time undergraduate, postgraduate taught or postgraduate research degree), the route by which misconduct will be investigated will normally be determined by whether the alleged misconduct took place during staff or student duties.
- 8.1.5. Misconduct in research includes acts of omission as well as acts of commission.
- 8.1.6. Allegations of misconduct in research will be judged by the standards which prevail in the country in question at the date that the behaviour under investigation took place.

## 8.2. Types of misconduct in research

- 8.2.1.The definitions used here are adapted from <a href="UK Research & Innovation's (UKRI) Policy and Guidelines on Governance of Good Research Conduct">Good Research Conduct</a>. Researchers **must** ensure that they do not commit any of the following acts:
- 8.2.2.**Fabrication** comprises the creation of false data or other aspects of research, including documentation and participant consent.
- 8.2.3. **Falsification** comprises inappropriate manipulation and/or selection of data, images and/or other contents.
- 8.2.4.**Plagiarism** comprises the misappropriation or use of others' ideas, intellectual property or work (written or otherwise), without acknowledgement or permission.
- 8.2.5. Misrepresentation includes:
  - Misrepresentation of data, such as by suppression of relevant findings, or knowingly, recklessly or by gross negligence presenting a flawed data interpretation;
  - Undisclosed duplication of publication, including duplicate submission of manuscripts for publication;
  - Misrepresentation of interests, including failure to declare material interests either of the researcher or of the research funders;



- Misrepresentation of qualifications and/or experience, including claiming or implying qualifications or experience not held; and/or
- Misrepresentation of involvement, such as inappropriate claims to authorship and/or attribution of work where there has been no significant contribution, or the denial of authorship where an author has made a significant contribution.
- 8.2.6.**Breach of duty of care** to includes, whether deliberately, recklessly or by gross negligence by:
  - Disclosing improperly the identity of individuals or groups involved in research without their consent, or any other breach of confidentiality;
  - Placing any of those involved in research in danger, whether as subjects, participants or associated individuals, without their prior consent, and without appropriate safeguards even with consent (this includes reputational danger where that can be predicted);
  - Not taking all reasonable care to ensure that the risks and dangers, the broad objectives and the sponsors of the research are known to participants or their legal representatives, and/or to ensure appropriate informed consent is obtained properly, explicitly and transparently;
  - Not observing legal and reasonable ethical requirements or obligations of care for human or animal subjects, human organs or tissue used in research, or for the protection of the environment; and/or
  - Improper conduct in peer review of research proposals or results (including
    manuscripts submitted for publication); this includes failure to disclose conflicts of
    interest; inadequate disclosure of clearly limited competence; misappropriation of
    the content; and breach of confidentiality or abuse of material provided in
    confidence for peer review purposes.
  - Breach of any express or implied confidentiality provision including provisions relating to externally awarded funding or research involving external organisations.
- 8.2.7. Failure to meet ethical, legal and professional obligations includes failure to meet the standards of relevant professional bodies (e.g. the General Medical Council) and standards and limitations applied to research by Research Funders or Research Ethics Committees. Failure to meet ethical, legal and professional standards may also comprise failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials.
- 8.2.8.Improper dealing with allegations of misconduct includes:
  - Failure to address possible infringements, including attempts to cover up misconduct or reprisals against whistle-blowers; and/or
  - Failure to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct.
- 8.2.9. The list of types of research misconduct above is not intended to be exhaustive. Honest errors and differences in, for example, research methodology and interpretations are not examples of research misconduct.

#### 8.3. Reporting misconduct in research



- 8.3.1.Allegations of research misconduct are managed by a <u>Named Person</u>, delegated by Senate to ensure appropriate action is taken.
- 8.3.2.A complaint of misconduct in research concerning a University member of staff or postgraduate research student must be made to the Named Person for an initial assessment of the nature and severity of the allegations.
- 8.3.3.A complaint of misconduct in research concerning an undergraduate or taught postgraduate student **must** be reviewed by the Head of Department in the first instance before a decision is made on the most appropriate route for dealing with the complaint. In making their decision, the Head of Department may seek advice from the Ethics and Integrity Manager, Named Person, or the Academic Registrar.
- 8.3.4. Cases of alleged misconduct involving registered students will be dealt with according to the procedures in <u>Senate Regulation Eleven: Regulations governing student discipline</u>.
- 8.3.5.In the case of a member of staff, the Named Person should contact the Ethics and Integrity Manager and the relevant Human Resources Business Partner (HRBP) immediately on receipt of an allegation of misconduct to initiate the appropriate process.
- 8.3.6.In the case of a postgraduate research student, the Named Person will contact the Dean of the Doctoral College or Head of Department /School (as appropriate) immediately on receipt of an allegation of misconduct to agree the appropriate process for investigating the allegations.
- 8.3.7. Where, in the view of the Named Person (in consultation with the Ethics and Integrity Manager, HRBP or the Dean of the Doctoral College or the Head of Department/School, as appropriate), it would be appropriate to manage the alleged misconduct informally, this may be done without recourse to the University's formal procedures.
- 8.3.8.All enquiries into alleged misconduct (including formal investigation, if any) will be conducted on the basis of confidentiality within the process (wherever possible), as well as of integrity and non-detriment, so that no party may suffer solely as a consequence of an allegation made in good faith.
- 8.3.9.The identity of the individual reporting serious research misconduct will be kept confidential wherever practicable. However, the identity of this individual may be revealed if, for example, it is deemed necessary in order to allow the person accused of misconduct to conduct their defence. If an anonymous complaint is received, the University will decide how to proceed, taking into account the nature and circumstances of the complaint.
- 8.3.10. A complaint may be made via an intermediary, but that intermediary **must** act solely as a conduit for the transfer of material between the complainant and the University, and **must not** seek to interfere with or influence in any way the intent or conduct of the case. Any person who is approached to act as intermediary who is not able to act in this manner **should** decline the request.
- 8.3.11. Where there is prima facie evidence that an allegation of research misconduct is made with vexatious or malicious intent, that allegation may be considered as a disciplinary matter. A complainant may be given an opportunity to respond if the



allegation is not accepted and if the complainant believes that they have been misunderstood or key evidence overlooked.

#### 8.4. Notification of misconduct in research to external organisations

- 8.4.1.The UKRI Policy and Code of Conduct on the Governance of Good Research Conduct states that, once an informal investigation begins, "Where an allegation of research misconduct is about someone funded by, or engaged with, UKRI (including acting as a supervisor for an UKRI postgraduate student or engaged with peer review activities), even if it is about work not connected with a grant from a UK Research Council, the case **should** be reported to the relevant Council when a decision to undertake an informal inquiry has been made i.e. that there is a reasonable case that research misconduct may have occurred [...] The Councils reserve the right to take appropriate action about any duties being performed for UKRI at any stage during the process." The University will comply with these requirements and notify UKRI of any allegations of misconduct which have proceeded to formal investigation.
- 8.4.2. The University will also comply with the regulations of any other Research Funder, professional association or similar body in the reporting of investigations or proven allegations of research misconduct.
- 8.4.3.If an allegation of misconduct in research involves staff and / or students from another organisation(s), the University can, at its discretion consult, and / or work with these others on a joint investigation or to agree joint actions on outcomes.

## 8.5. Investigation of misconduct in research

- 8.5.1.The non-contractual Procedure for the Investigation of Misconduct in Research, published by the UK Research Integrity Office, will normally be used to investigate cases of alleged misconduct in research involving University staff, as recommended by the University's Discipline (Ordinance Policy). The principles of this procedure are incorporated in the University's Guidance for Researchers on Research Misconduct, and Standard Operating Procedures for the Management of Research Misconduct Investigations.
- 8.5.2.Where an investigation relates to the conduct of a study sponsored by the University of Leicester and under the oversight of the Research Governance Office, the investigation will be dealt with in accordance with SOP S-1016 and the University's Guidance for Researchers on Research Misconduct, reported to the University Research Sponsorship Committee and escalated as required.
- 8.5.3. Where an investigation involves an international collaborative project, the non-contractual <u>OECD code for Investigating Research Misconduct Allegations in International Collaborative Research Projects</u> will be used as a guide, where agreed.
- 8.5.4. Without prejudice to the presumption of innocence, the Named Person (in consultation with HR) will consider whether it would be appropriate to appoint a replacement supervisor for any researchers or other staff linked to an investigation, for the duration of any investigation, in order to protect their interests and that of the member(s) of staff under investigation.



- 8.5.5.Should the complainant, respondent or any key witnesses refuse to co-operate with an investigation, or leave the University during an investigation, the University will be responsible for deciding whether to continue with or terminate the investigation, taking into account the specific details of the case.
- 8.5.6.If during the investigation of a complaint, evidence of misconduct in research is found distinct from that forming the basis of the initial investigation, the University will be responsible for deciding whether or not to investigate further, either as part of the initial investigation or as a separate investigation.

#### 8.6. Penalties or actions taken in the case of misconduct in research

- 8.6.1.If research misconduct is found following the completion of an investigation, supplemental actions may be agreed in addition to any disciplinary or legal procedures. These may include:
  - Retraction or correction of articles in published materials;
  - Withdrawal/repayment of Research Funding;
  - Notifying patients/patients' doctors of any potential medical issues that may arise
  - Notification of misconduct to regulatory bodies (such as the MHRA, the Healthcare Commission, the Home Office, professional bodies, etc.)
  - Notification to professional bodies, in particular if the concerns relate to Fitness to Practise
  - Notifying other employing organisations
  - Notifying other organisations involved in the research including funders
  - Adding a note of the outcome of the investigation to a researcher's file for any future requests for references
  - Review internal management and/or training and/or supervisory procedures for research
  - The making of any public statement necessary to protect the good name and reputation of the University
  - Addressing and remedying any research misconduct that may have taken place
  - Reporting on any procedural or organisational issues which should be reviewed by the institution
  - Remedial training, mentoring and monitoring when the person(s) involved continue to work or study at the University
- 8.6.2.The University reserves the right to report proven allegations of research misconduct against its staff, honorary and emeritus staff, former staff and current and former registered students to potential, new and subsequent employers. Where employees or students of another institution are involved in a collaborative research project with the University and are implicated in an allegation or finding of research misconduct, the University reserves the right to notify the home institution of those involved.



# 9. Annex 1: Policy, Guidance and Codes of Practice

- 1.2. University of Leicester policies, guidance and codes of practice can be accessed via the <u>University Policy Register</u>.
- 1.3. Links to external policy, guidance and legislation can be found on the <u>Research Ethics</u>, <u>Governance and Integrity</u> webpages.