# UNIVERSITY OF BIRMINGHAM CODE OF PRACTICE FOR RESEARCH

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#### Introduction

The Code of Practice for Research (herein 'The Code') defines the University's policies and expectations in relation to the conduct of research under its auspices.

The University is committed to research excellence and to the rigorous pursuit of new knowledge. As such it is committed to maintaining the highest standards of scholarly and scientific integrity in its research. It expects all Researchers to work to these standards.

As described in the University's <u>Code of Ethics</u>, Researchers must be honest, accountable and lawful in respect of their own research as well as that of their students and others working with them. Responsible ethical conduct is expected in all aspects of research, including applying for funding, experimental design, generating and analysing data, using equipment and facilities, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others.

The Code reiterates the <u>commitment to academic freedom</u> found in the University's Ordinances, clarifies University requirements, and offers information on the University's facilities for advice on regulatory and ethical issues. The research misconduct process allows for allegations to be assessed prior to the initiation of formal disciplinary investigation in order to distinguish serious cases from obvious mistakes or clearly vexatious claims.

All research is required to undergo the appropriate research ethics review process. For staff and postgraduate students, this process is managed by the relevant specialist subject ethical review committees reporting into the Research Governance, Ethics and Integrity Committee. This approach promotes best research practice, takes account of subject specific issues, and secures the interests and welfare of research participants, researchers, and other stakeholders.

Where research falls within specific regulatory and legislative frameworks (e.g. the UK Policy Framework for Health and Social Care, the Human Tissue Act 2004, the Medicines for Human Use (Clinical Trials) Regulations 2005 or the Animals (Scientific Procedures) Act 1986), researchers are required to comply with the relevant regulatory requirements and the University's specific research ethics and governance processes, managed by specialist committees and reporting into the institutional Research Governance Ethics and Integrity Committee. Researchers affected by these requirements should contact the Research Ethics, Governance and Integrity team (REGI) for support in the first instance.

<u>Allegations of research misconduct will be investigated by the University</u>, and appropriate actions taken.

This Code also covers the following areas:

- Due Diligence of proposed research partners in the context of international research (Section 3)
- Safeguarding in the context of research (Section 3)
- Management of research data (Section 4)
- Assignment of intellectual property (Section 6)
- Conflicts of interest (Section 7)
- Export Controls (Section 10)

This document should be read in conjunction with the relevant Conditions of Employment, <u>University Ordinances and Regulations</u>, the University's Codes of Practice (including but not limited to the <u>Code of Ethics</u>), and any other policies, procedures or guidance as may be issued by the University from time to time. Any special standards of work performance or conduct imposed by law or by the University from time to time in relation to particular categories of research, for example clinical research, are deemed to be included in this Code in its application to persons engaged in that research in the University.

## 1. Definitions

Term	Definition
Adverse Event	An event which results in or may result in harm or damage to the interests the Researcher, the research participants, the University (including its reputation), society, the environment or in a failure to maintain appropriate standards of animal welfare.
AWERB	Animal Welfare and Ethical Review Body
Author Accepted Manuscript (AAM)	The final author-created version of a Research Publication manuscript which includes change made after peer review and has been accepted for publication.
BMSU	Biomedical Services Unit
Chief Investigator (applies to medical research)	The person who takes overall responsibility for the design, conduct and reporting of a study if it is at one site; or if the study involves researchers at more than one site, the person who takes primary responsibility for the design, conduct and reporting of the study, whether or not that person is an investigator at any particular site.  For CTIMPs (see definition) the Chief Investigator must be an authorised health professional.
0'' '' 0' 1	authorised health professional.
Citation Clubs	A formal or informal agreement between two or more individuals to cite each other's work in order to artificially increase their scores on citation indexes.
Clinical Trial	For clinical trials using an investigational medicinal product.
	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining its (their) safety and/or efficacy.
	For all other clinical trials:
	Prospective biomedical research on human subjects that is conducted to allow safety (or more specifically, information about adverse drug reactions and adverse effects of other treatments) and efficacy data to be collected for health interventions. Examples include devices, surgery and radiotherapy trials.
The Code	This Code of Practice for Research

Code of Ethics	The University's Code of Ethics (as amended from time to time).
Competent Authority	The agency in a given country which authorises and licenses medicinal products and is able to authorise CTIMPs. In the United Kingdom this is the Medicines and Healthcare products Regulatory Agency (MHRA).
CTIMP	A Clinical Trial of an Investigational Medicinal Product is a study that tests the safety and/or efficacy of a medicine/foodstuff/placebo in humans, as defined by the Medicines for Human Use (Clinical Trials) Regulations 2004
СТОС	The Clinical Trials Oversight Committee
DPA	The Data Protection Act 2018 (as subsequently amended).
Emeritus Professor	A Professor of the University on whom the title of "Emeritus Professor" has been conferred on or after their retirement.
Essential Documents	Those documents which individually and collectively permit evaluation of the conduct of a research project and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator and Sponsor with standards of Good Clinical Practice (where applicable) and with all applicable regulatory requirements.
Establishment Licence	A licence granted by the Home Office under section 2B of the Animals (Scientific Procedures) Act 1986, which is required to carry on specific undertakings relating to research with animals as laid out in the Act.
Establishment Licence Holder	The holder of the University's Establishment Licence as issued by the Home Office.
Funder	The individual(s) or organisation(s) which pays wholly or partially for the conducting of a research project.
Good Clinical Practice	An international scientific quality standard for the design, conduct, monitoring, auditing, recording, analysis and reporting of Clinical Trials.
GDPR	The General Data Protection Regulation means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data as it forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by Schedule 1 to the Data Protection, Privacy and Electronic Communications (Amendments etc) (EU Exit) Regulations 2019 (SI 2019/419).
Intellectual Property Rights	
Misconduct in Research NHS REC	Misconduct in research is a failure to comply with the provisions of this Code, as outlined in detail in paragraph 13.1 below.  The national Research Ethics Service. This is the part of the Health Research Authority that manages the research ethics review required to conduct research on NHS patients or Social Care clients.

Post-Review Manuscript	The AAM term has largely evolved in the context of journal publishing and does not necessarily fit the more complex editorial process used through the monograph publishing process. Post-Review Manuscript is used in this policy to describe a version of the text of a monograph or chapter which has been through a peer review / editorial process and has been finalised short of final layout and typesetting.
Principal Investigator [/University Lead]	A (senior) person in the University who takes responsibility for the conduct and delivery of those parts of the study, which are either carried out at or managed/overseen by the University. Normally this would be an academic researcher. For grant funded research, this will by default be the grant holder.
	Please note: the term has a different meaning in the context of clinical trials where the Principal Investigator will be the person who takes responsibility at a particular research site and the Chief Investigator is the person who takes responsibility for the trial as a whole (see above). In that context, the University uses 'University Lead' in place of 'Principal Investigator'.
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial or study. The protocol usually also gives the background and rationale for the trial, but these could be provided in other protocol referenced documents.
Registered Student	Any person currently registered for the receipt of instruction in the University. It includes both undergraduates and postgraduate Registered Students.
Researcher	Researcher means:
	All Staff, Emeritus Professors and Registered Students of the University who are undertaking or involved in any aspect of research at any level;
	External research collaborators who are undertaking or involved with research in connection with, or as part of, the University;
	Where someone collaborates with the University to conduct research, but is not connected with or part of the University, they will also be expected to abide by this Code or an equivalent code provided by their employer.
Research Publications	Journal articles, conference papers, monographs, book chapters, edited collections formally published with an ISBN for an academic audience, and formal reports which communicate research outcomes authored or co-authored by a Researcher. This includes pre-prints, Author Accepted Manuscripts and Post-Review Manuscripts.
Research Publications Policy	The University's Research Publications Policy
RSSD	The University's Research Strategy and Services Division
Scholarly Works	Works created to communicate or evidence a person's research and/or scholarship which are not reasonably likely to have potential commercial significance, and which shall for the avoidance of doubt (regardless of their actual, potential or perceived commercial significance):

	Include the following works:	
	<ul> <li>Student theses and work submitted by Students in respect of the University's formative and summative assessments</li> <li>Research Publications</li> <li>Trade publications</li> <li>Research summaries for a professional or lay audience</li> <li>Films, videos, sound recordings and transcripts, and in each case transcripts thereof</li> <li>Musical compositions and scores</li> <li>Creative writing and dramatic works including novels, poetry, songs, plays, works of fiction and non-fiction</li> <li>Works of choreography</li> <li>Works of art, including <ul> <li>graphic works (whether physical or digital) including paintings, drawings, designs, diagrams, maps, charts or plans, engravings, etchings, lithographs, woodcuts or similar works, photographs, sculptures or collages, all irrespective of artistic quality</li> <li>work of architecture including buildings or models for buildings, including part thereof,</li> <li>works of artistic craftsmanship</li> </ul> </li> <li>Other works of artistic imagination not described above</li> </ul>	
	Exclude the following works:	
	<ul> <li>Research data of any form</li> <li>Software and code</li> <li>Protocols and questionnaires forming a component part of or which are ancillary to Research Publications</li> <li>Research tools and protocols including, without limitation, surveys, questionnaires, diagnostic methods, standard operating procedures, databases, assays.</li> </ul>	
Sponsor	Individual, organisation or group taking on whole or [shared] responsibility for securing the arrangements to initiate, manage and finance a clinical study (as required by the UK Policy Framework for Health and Social Care and the Medicines for Human Use (Clinical Trials) Regulations 2004).	
Sponsorship	Agreement from an eligible individual, organisation or group that they will take on the responsibilities of Sponsor in relation to a study.	
Staff	All persons employed in the service of the University. For the purpose of this Code, the term "Staff" also extends to honorary staff (e.g. honorary lecturers) engaged by the University, visiting staff and other individuals engaged by the University to provide services to the University.	
UK Policy Framework for Health and Social Care	UK Policy Framework for Health and Social Care (as amended from time to time).	
UKRI	UK Research and Innovation	
University	The University of Birmingham	

#### 2. Application of the Code

- 2.1. The Code applies to all Researchers.
- 2.2. All Researchers must familiarise themselves with this Code and abide by it.
- 2.3. Researchers are responsible and accountable for their own conduct and for abiding by the Code.
- 2.4. The University will draw attention to the Code and to relevant training and development modules in its induction processes for newly appointed Researchers to ensure that they are aware of best practice requirements. In addition, supervisors of Registered Students have a responsibility to ensure that their Registered Students are aware of this Code and to provide oversight of their research in order to ensure that the Code and best research practice are followed.
- 2.5. Heads of College have a responsibility to ensure compliance with the Code in their Colleges. Heads of School share the same responsibility at School level. Principal Investigators have that responsibility at project level (see paragraphs 3.2, 3.3, and 3.4 below).
- 2.6. Registered Students are responsible and accountable for their own conduct and for abiding by the guidance provided by their supervisors and this Code.
- 2.7. The University's Research Governance, Ethics and Integrity Committee will review the Code on every two years, in consultation as appropriate with relevant individuals or groups in preparation for approval by the University's Research Committee. The review will take into account the Code's implementation, changes and recommendations from external research Funders, Regulators, Acts of Parliament and other regulations.
- 2.8. Where any proposed change to this Code would affect Staff Terms and Conditions of Employment, the University will follow the appropriate normal procedures of consultation and/or negotiation.
- 2.9. The University recognises and protects the principle of academic freedom in its Ordinances (see Ordinance 3.18) and this Code is not intended to restrict the academic freedom of Staff. However, each member of Staff is expected to exercise their academic freedom in a manner consistent with this Code, other University Ordinances and Regulations, the University's Codes of Practice and other regulations imposed by law from time to time.

#### 3. Integrity and Accountability

- 3.1 The University is committed to working in line with research related Concordats such as the 'Concordat to support Research Integrity' and the 'Concordat to Support the Career Development of Researchers' that outline the responsibilities and commitments of stakeholders in research with respect to research integrity.
- 3.2 All Researchers owe a duty of accountability to the University, to the participants in their research, and to their research funders, commensurate with their involvement in that research. Researchers are responsible for the conduct of their part in any research and for providing direction for the activities of other Researchers under their supervision.

- 3.3 For any given project there must be a Principal Investigator who retains overall responsibility for the research, and is accountable for its quality, integrity, finances, and ethics. In the case of a project or study with a sole investigator, that person is de facto the Principal Investigator. For projects by a Registered Student, the lead supervisor of that Registered Student will be the Principal Investigator. See the Code of Practice on the Supervision and Monitoring Progress of Postgraduate Researchers (accessible from the Codes of Practice, Policies and Guidance web page) for further information about arrangements for student supervision. Please note: different terminology is in use for clinical research.
- 3.4 The Principal Investigator of any research should identify and communicate clear roles and duties for all those involved in the research and should ensure that all involved are informed of their responsibilities.
- 3.5 The Principal Investigator is accountable for the duties and responsibilities set out below, noting that this is not exhaustive list of duties:
  - (a) the necessary ethical basis of the research and the research design;
  - (b) the safety of all involved in the research;
  - (c) the suitability of the working environment and adequate provision of equipment and facilities:
  - (d) as appropriate, the completion of a health and safety risk assessment and discussion of any potential hazards with the School and/or College Health and Safety Coordinator:
  - (e) the robust financial management of their projects in accordance with the requirements specified by the Funder, and for seeking to provide the optimum value for the public, private or charitable Funders who have invested in them;
  - (f) the effective project management of their project to agreed project plans and appropriate quality standards, including the establishment of appropriate governance structures, oversight and reporting mechanisms, and the timely delivery of any scheduled outcomes;
  - (g) compliance with the terms of any ethics review or favourable ethical opinion or governance approvals, contracts or agreements with third parties in relation to the research including, but not limited to, any deliverables and the Protocol;
  - (h) use of reasonable endeavours to ensure the observance of University and third- party Intellectual Property Rights;
  - (i) management of research data in accordance with the GDPR, the DPA and any other external or internal legislative provisions, conditions or guidelines that may apply to the handling of personal information or research data from time to time (see paragraph 4 below). This includes, but is not limited to, the requirement to retain documents relating to a research project and make them available to internal and external auditors/monitors and regulatory bodies;
  - (i) timely and appropriate dissemination of research findings;
  - (k) completion of appropriate professional development relevant to the research, and ensuring that all Researchers are appropriately qualified by training and experience to carry out their role in the research;

- (I) maintenance of personal records of research progress, including authorised laboratory books, to the recommended or required standards;
- (m) maintaining confidentiality in order to achieve protection of Intellectual Property Rights, commercially sensitive data, personal data and other confidential information where appropriate;
- ensuring research participants participate voluntarily and free from any coercion and are properly informed of any risks, the broad objectives and of the identity of any Sponsors and Funders of the research;
- use of all best endeavours to avoid unnecessary harm to participants, other people, animals and the natural environment, having taken due account of the foreseeable risks and potential benefits of the research;
- (p) awareness of the ways in which research derives from and affects the work of others, and respecting the rights and reputation of others;
- ensuring the necessary contracts of employment and other agreements for activities with third parties (e.g. NHS Honorary Research Contracts or Letters of Access) are in place and complied with;
- ensuring the adequate provision of appropriate facilities, resources, expertise, and any necessary protection, for example insurance, prior to the commencement of the research;
- (s) for applicable clinical research, compliance with the University's Quality Management Systems outlined in the University's Research Quality Manual (accessible via the <u>Clinical Research Quality Management Systems</u> web page). The categories of work to which this applies are detailed within the Research Quality Manual;
- (t) recording of research methods and data in a way that allows for independent verification of the integrity of the research process and outputs;
- (u) compliance with applicable regulatory obligations (whether under UK, EU, USA law or otherwise) such as these apply to research including the Export Control Act 2002 and Export Control Order 2008 (and any related, other, ancillary, subordinate, and replacement legislation) (together 'Export Control legislation').

Each of these duties, with the exception of (u) 'Export Controls', may be delegated to appropriate persons, but the Principal Investigator must retain oversight and remains accountable. Principal Investigators (including without limitation during the supervision by them of PhDs students) are responsible for compliance with Export Control legislation and cannot delegate this responsibility. Researchers have a responsibility to carry out their research in accordance with any reasonable instructions given by the Principal Investigator in the exercise of their duties.

3.6 Where a Researcher (including the Principal Investigator) has concerns about whether the obligations of accountability as set out in paragraph 3.4 (above) can be met, is in doubt about the applicability of provisions of the Code to their part in any research, about the appropriate course of action to be adopted in relation to it, or requires advice on individual grant or contract terms, advice should be sought from colleagues in the <a href="Research Strategy">Research Strategy</a> and <a href="Services Division (RSSD)</a>. A Registered Student who has any questions about this Code should in the first instance raise these with their Supervisor.

3.7 Researchers must familiarise themselves with the terms of any collaboration, funding or other agreements (grant or contract), protocol and ethical approval related to their work, and ensure that any research undertaken complies with those terms and conditions.

For example:

- (a) Researchers undertaking research funded by UK Research and Innovation must abide by UKRI's principles, policy and guidelines for good research conduct.
- (b) Researchers undertaking research funded by the EU under Horizon 2020 must comply with the ethical standards and guidelines of Horizon 2020 (see <a href="Horizon 2020">Horizon 2020</a> (see <a href="Horizon 2020">Horizon 2020<a href="Horizon 2
- 3.8 Funding received by the University from external funders based in another country may be subject to that country's local rules relating to conflicts of interest and other relevant matters. Both the University and the Researchers involved in the research or delivery of a project may be required to comply with those rules. On applying for funding from a relevant institution or on commencement of work on such a project, Researchers will be notified of the relevant rules and be asked to sign a declaration confirming that they agree to comply with them. Failure to do so may result in the suspension of the activity as required by the relevant rules. Failure to comply with the rules may result in the suspension or reorganisation of any relevant activities or the commencement of disciplinary action as appropriate.
- 3.9 Many UK public and charity funders require grant recipients to undertake appropriate due diligence on proposed external collaborators/sub-contractors/partners, and the majority of such funders require specific due diligence checks to be conducted where the research proposes to engage with organisations in Low Middle Income Countries (LMIC). In the latter case, funders require that such checks include a review of compliance with Overseas Development Aid Funding rules (ODA) and that these are completed prior to the commencement of research and/or before any funding or resources are sent to the LMIC. Support to undertake such due diligence is provided by RSSD.
- 3.10 As outlined throughout this Code, the University expects its researchers and our partners, sub-contractors, and collaborators, to adhere to the highest standards of research integrity.

We take seriously our responsibility for creating research environments that are safe for all of our staff and research participants, free from sexual exploitation, abuse and harassment, bullying, psychological abuse, and physical violence.

These standards apply to our research wherever it is delivered, in the UK, or internationally. In all of these circumstances, all staff that are involved in the delivery, or support of research, are required to read and comply with the standards outlined in this Research Code of Practice, and with all institutional policies, including:

- Safeguarding Policy
- Code of Ethics
- Harassment and Bullying Policy (sharepoint.com)
- Whistle-Blowing Policy
- Health & Safety Policy
- Fairness & Diversity Policy
- Anti-Bribery & Corruption Policy
- The University of Birmingham Data Protection Policy

Information Security Policy - Policies and Procedures (sharepoint.com)

Specifically with regards to research that is proposed to be delivered in international contexts, a risk assessment, identifying and ensuring appropriate mitigation of risks to staff and research participants must be completed and approved via the appropriate channels, in accordance with the <u>University's Health & Safety Policy.</u>

Whilst every individual conducting work covered by this Policy is responsible for meeting the requirements within it, the Principal Investigator of a research project is ultimately responsible for ensuring compliance with the institutional policy framework; this includes ensuring that an appropriate risk assessment and safeguarding review are undertaken, and that any risks and safeguarding issues are appropriately mitigated, monitored, and revised, as appropriate.

#### 4 Research Data

- 4.1 Researchers must comply with the University's Policy on Research Data Management (Research Data Management Policy), which provides more detailed guidance on this matter and definitions of Research Data and Open Data.
- 4.2 Researchers should also comply with any applicable funder policies concerning research data management.
- 4.3 Researchers must keep clear, detailed and accurate records of the research procedures they follow and the results obtained, including interim and final results.
- 4.4 It is the duty of the Principal Investigator in any research to comply with the GDPR and the DPA and with any data protection and/or information security requirements which apply to the research. The GDPR and the DPA apply to all processing of personal data (which includes the obtaining, processing, sharing, storage and destruction of personal data). Information and resources on data protection are available on the <a href="Legal Services">Legal Services</a> intranet page and advice may be obtained from <a href="Legal Services">Legal Services</a>
- 4.5 Appropriate technical and organisational measures must be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data in compliance with the DPA and GDPR, the University's IT Security policies, standards and guidance and with any contractual or other requirements which apply to the research. Information and resources on IT security is available on the IT Services intranet page.
- 4.6 Research data created by Staff and Emeritus Professors remains the property of the University when a researcher leaves unless a prior agreement is in place with a third party re data ownership. Where research data has been made Open Access on conclusion of a project, the researcher in question may access it in the normal manner; if not an access request will be required. Research data created by Staff and Emeritus Professors that is included in a Research Publication shall remain the property of the University.
- 4.7 The University will retain and curate Research Data arising from research undertaken by Registered Students, Emeritus Professors, and Staff in the course of their employment (or for Staff who are not employees, in the course of their duties for the University), in accordance with terms and conditions of Funders, good practice guidance, contractual obligations and the University's policies.
- 4.8 Research data created by Research Students will remain the property of the student unless any of the circumstances set out at section 6.2(b) of this Code apply.

#### 5 Publications

- 5.1 The University encourages its Researchers to disseminate the findings of their research through appropriate and timely publication. For the purposes of this policy, 'Publication' is used in its broadest sense to mean the widespread dissemination of research outcomes to a broad (often but not always public) audience. This includes the formal distribution of Research Publications via the services of commercial, society and other scholarly publishers, often following peer review. However, it also includes the dissemination of other forms of Scholarly Works and less formal, often non-peer reviewed means of communicating research outcomes including, but not limited to, websites, databases, preprint servers, working papers, online theses, press releases, media briefings, exhibitions and other events.
- 5.2. Ethical considerations apply to the production of all categories of publications. The University expects Researchers to abide by the University's core principles of openness, transparency and accountability and adopt appropriate ethical and professional standards and responsibilities in their publications, as set out in the Research Publications Policy.
- 5.3. All Researchers are required to include a record of their Scholarly Works in the relevant University repository and to ensure that an appropriate full-text version of each Research Publication is deposited in that repository and made Open Access in line with the University's Research Publications policy as implemented and any prevailing funder mandate(s). As of the date of this policy, <a href="Pure">Pure</a> is the University repository for Scholarly Works. Exceptions to the use of Pure are a) Theses, which must be deposited in the eTheses repository, b) Working papers, which can be deposited in the ePapers repository at the author's discretion. Section 4 deals with the recording and deposit of Research Data.
- 5.4 There is a fundamental ethical obligation on authors to acknowledge and attribute external sources of information. Citation of sources should be carried out in accordance with an appropriate referencing system (e.g. the Harvard referencing system, or the house style of the relevant publisher and/or the normal practices of the discipline concerned). Citation not only gives credit to the work of others, but also enables readers to identify elements in the text and therefore recognise the contribution of the author or authors in the context of previous work. Failure to cite sources including responsible use of AI could constitute plagiarism and may be subject to the instigation of the relevant University disciplinary procedures (see 5.11 of this Code).
- 5.5 Plagiarism is a form of cheating and is a serious academic offence that constitutes misconduct. The Code of Practice for Staff on Plagiarism and the Code of Practice on Plagiarism (applicable to students) and the associated Guidance applies to all research work (the current versions are accessible via the <u>Plagiarism information for staff intranet page</u> and the <u>Plagiarism intranet page</u>.
- 5.6 The University does not endorse citation arrangements, which are contrary to academic conventions (such as Citation Clubs or the unnecessary use of self-citation). Membership of Citation Clubs may be regarded as misconduct as set out in clause 13.1.4(iii) or 13.1.4(iv) below.
- 5.7 It is in the interests of Researchers and the University that good practice in the matter of co-authorship is disseminated, understood and followed. Researchers should familiarise themselves with the conventions of their particular discipline and any specific guidelines that may be issued by the University from time to time.
- 5.8 Only those who have made what might reasonably be regarded as a significant contribution to the relevant research should be named as authors. Any person who has

materially contributed through conceiving, executing or interpreting at least part of the relevant research should be given the opportunity to be included as an author of a publication derived from that research. Accepting the status of co-author implies a full commitment to having one's name and reputation fully associated with the content of the publication. Researchers should, where applicable, follow guidance relevant to the discipline and/or journal in respect of naming authors.

- 5.9 Any person who has contributed to at least part of the relevant research, but who does not fulfil the criteria set out in clause 5.8 above on authorship should not be included as an author of a publication derived from that research, but their contribution should be acknowledged in accordance with clause 5.10.
- 5.10 There is a general ethical obligation that the contributory efforts of persons who have helped in the work being reported in a publication should be identified and acknowledged in it. It may, therefore, be appropriate to identify those who have *assisted* substantively in the work presented in a publication. This may include Funders, colleagues within and outside the University who have given advice and any others who have facilitated the collection of material or data on which the publication is based or who have assisted in producing the publications. Those identified should be approached for permission if it is intended to acknowledge their assistance in the publication, and they should be offered the opportunity of seeing the publication.
- 5.11 A publication which is substantially similar to other publications derived from the same research must contain an appropriate reference to the other publications. A Researcher must disclose to a publisher at the time of submission: (a) substantially similar work, which is being submitted to another publisher at the same time; or (b) work which has been previously published.
- 5.12 Authors should be aware that in contract and collaborative research it may be necessary to seek permission for publication from all parties to the contract in advance of submission of the work to a publisher.
- 5.13 In order to ensure that clinical trial results are made available, the Chief Investigator must ensure that all planned clinical trials are registered on a publicly accessible database, with a summary of the trial protocol, before the first participant is recruited. Past trials that were not registered should be registered retrospectively. The Chief Investigator must ensure a summary of results is made publicly available where the trial was registered, within one year of completion of the trial. Summary results from all past trials of medicines currently in use should be made publicly available on a register. Summary results include information on the primary and any secondary outcomes measured and statistical analysis.
- 5.14 All efforts should be made to preserve the accuracy of the published research record. In particular, if significant errors in research data should emerge then Researchers are required to retract or correct any of their publications reporting or based on those data.

## 6. Intellectual Property

#### Intellectual Property Rights ownership – Staff and Emeritus Professors

6.1 Unless a prior contractual arrangement assigns such rights to a Sponsor or Funder, the University will own the Intellectual Property Rights arising from research undertaken by Emeritus Professors and Staff in the course of their employment (save for in respect of Staff who are not employees, who assign to the University absolutely the Intellectual Property Rights arising from research undertaken by them in the course of their duties for the University). In the case of external research collaborators, the relevant collaboration

agreement covering their work with the University will set out the ownership of Intellectual Property Rights.

## Intellectual Property Rights ownership - Registered Students

6.2

- (a) Registered Students will own the Intellectual Property Rights in all Scholarly Works which they create in their capacity as a Registered Students.
- (b) Other than in respect of Scholarly Works, Registered Students own the Intellectual Property Rights arising from their engagement with the University in their capacity as a Registered Students except where:
  - such Intellectual Property Rights were invented, created or made:
    - using funding received from the University (unless otherwise agreed in writing by the University); or
    - under circumstances in which Staff are entitled to joint rights of ownership in the intellectual property:
  - a prior contractual arrangement assigns such Intellectual Property Rights to a Sponsor or Funder.

In the event of which, Registered Students must make an assignment of all Intellectual Property Rights to the University, Sponsor or Funder (as appropriate). See Regulation 5: Admission and Registration (Section 5.4 Intellectual Property) for further details.

- (c) A Registered Student who creates a Research Publication in their capacity as a Registered Student may elect to submit that Research Publication to the provisions of the Research Publications Policy, in the event of which they shall contact Library Services' Open Access and Copyright experts for further advice.
- (d) For the avoidance of doubt, where an individual who is a Registered Student is also a member of Staff, the provisions of Sections 6.3, 6.4, 6.7 and 6.8 of this Code shall apply to any Intellectual Property Rights created by that individual in their capacity as a member of Staff.
- 6.3 In consideration of the mutual obligations set out in this Code

#### Ownership of Scholarly Works

(a) The University assigns to any Staff and/or Emeritus Professors who create or come to create any Scholarly Work absolutely the entire copyright and all other rights in the nature of copyright subsisting in such Scholarly Work. This means that any such Staff or Emeritus Professors who created the relevant Scholarly Work shall own such copyright. For the avoidance of doubt, where multiple Staff or Emeritus Professors have created a Scholarly Work, those individuals shall own the relevant copyright jointly in equal and indivisible shares.

## Licence of Scholarly Works other than Research Publications

(b) The relevant Staff and/or Emeritus Professors grant to the University a non-exclusive, perpetual, irrevocable, royalty-free, worldwide licence (including the right

to sub-license to third parties as further below) to use and modify the copyright and all other rights in the nature of copyright subsisting in the relevant Scholarly Work for its educational, research, teaching, administrative and other reasonable purposes. For the avoidance of doubt, 'other reasonable purposes' include but are not limited to depositing accepted manuscripts of Scholarly Work in the institutional repository to support the University's aims for immediate open access and/ or depositing other materials of a scholarly nature where required for compliance with external funding bodies.

#### Licence of Research Publications

(c) In line with the Research Publications Policy and any exceptions therein, the relevant Staff and/or Emeritus Professors grant a suitable public licence to the copyright and all other rights in the nature of copyright subsisting in Research Publications. The specific public licence required will vary, and further information on the implications of this licence can be found in section 4.1 of the University's Research Publications Policy.

## Assertion of authorship and copyright statement

6.4 All Scholarly Works and other material issued by Researchers should bear an appropriate assertion of authorship and a copyright statement.

The following format is advisable for Scholarly Works other than Research Publications (the format for Research Publications is set out in section 4.3 of the Research Publications Policy):

© (Author(s) full name(s)), (year of publication), (Orcid ID), affiliated to (department/School/ College), The University of Birmingham. (Subject to alicence granted by the Author to The University of Birmingham)

## Potential commercial significance

- 6.5 In the event that an invention or discovery with potential commercial significance is made in the course of a research project carried out as part of Researchers' normal university activities, the procedures to be followed are set out in the following University regulations accessible from the Regulations intranet page:
  - (a) University Regulation 3.15;
  - (b) Regulation 5.4:
  - (c) Registered Students involved in research are expected to comply with the requirements of Regulation 3.15;
  - (d) Appendix 6 of the <u>Conditions of Employment Governing Academic and Academic-related Staff</u>
- 6.6 Where an invention or discovery with potential commercial significance has been made in the course of research:
  - (a) Researchers are required to make appropriate notification to University of Birmingham Enterprise Ltd (<a href="mailto:info@enterprise.bham.ac.uk">info@enterprise.bham.ac.uk</a>, <a href="https://www.birmingham.ac.uk/partners/enterprise/index.aspx">https://www.birmingham.ac.uk/partners/enterprise/index.aspx</a>, 0121 414 9090), and the Head of College as set out in Regulation 3.15 or Regulation 5.4.

- (b) Staff and Registered Students are reminded of the need to maintain confidentiality regarding the results of the research pending legal protection in accordance with any instructions or advice from University of Birmingham Enterprise Ltd (the wholly owned subsidiary of the University with sole responsibility for the exploitation of the University IP).
- (c) Researchers are required to familiarise themselves with and to abide by the terms relating to intellectual property and confidentiality in any grant, contract or collaboration agreement relating to their research projects. Breaches of confidentiality may result in actions for recovery of losses from a Funder or collaborator against the University and the individual concerned.

#### Researchers leaving the University

6.7 With regards to Researchers who leave the University, intellectual property developed during their employment which is owned by the University or has been assigned to a research funder by contract, remains the property of that organisation. It may not be divulged to third parties without permission from the owner of the intellectual property unless it is already in the public domain. Information received from third parties under terms of confidentiality whilst in the University's employ remains confidential, and breaches of such confidentiality may render the Researcher liable to claims by the owner of the information.

## Peer review and confidentiality

6.8 When peer reviewing research proposals or Scholarly Works (including manuscripts submitted for publication), Researchers must protect the confidentiality of information provided, disclose any conflicts of interest and any areas of limited competence, and (notwithstanding the generality of section 13 of this Code) must not misuse or misappropriate the material being reviewed or any part of it.

#### 7. Conflicts of Interest

- 7.1 Researchers in the exercise of their functions should not be constrained to reach any particular conclusion or to make any particular recommendations. However, in some situations a Researcher may find themselves in a position where there is an actual, potential or perceived conflict of interest which could influence the Researcher in reaching a particular conclusion. The Researcher should follow the guidelines outlined in the <a href="Protocol on Conflicts of Interest">Protocol on Conflicts of Interest</a> and the <a href="Bribery Act Policy">Bribery Act Policy</a>. Failure to declare known conflicts of interest may be deemed misconduct.
- 7.2 Researchers must comply with any direction made by the University in relation to a personal conflict of interest in research.

## 8. Ethics Review

- 8.1 As stated in the University Code of Ethics, responsible ethical conduct is required in all aspects of research and all research is required to go through the appropriate ethics review. The University's research ethics review requirements are designed to support researchers in this and are described below. Principal Investigators must engage with <u>University research ethics systems</u> and ensure that all research is submitted to the correct review process.
- 8.2 University Research Ethics Review

- (a) <u>University research ethics review processes</u> must be used for research involving people or their data that does not require NHS (or other mandatory) ethics committee review.
- (b) The processes provide a robust review of research, but are risk-adapted to enable a proportionate review of low-risk research. All Staff and Registered Students' research projects in receipt of external funding must first be registered with the Research Ethics, Governance and Integrity team, before seeking any appropriate ethics review as required (via the initial project registration process).
- 8.3 An appropriate research ethics review independent of the research team and completion of study-appropriate due diligence processes is required for all University research (including any Registered Student's research project) where:
  - (a) People are involved as data sources (e.g. as interviewees), or as the subject of the research. This includes any research where people's data are collected or analysed, or where blood, tissue or other biological samples are collected, stored or analysed. This includes secondary data analysis and analysis of anonymised data sets;
  - (b) The research presents a potential risk to the environment, society or the reputation of the University;
  - (c) The research presents a risk to the commercial interests of another organisation or deals with confidential or commercially sensitive information belonging to a third party; or
  - (d) The research presents other material ethical concerns.
- 8.4 As regards Registered Students whose research projects require research ethics review:
  - (a) The academic supervisor of the research is responsible for ensuring that the Registered Student is informed of the requirements for regulatory and/or ethics review that apply to their work, and for ensuring that these are met.
  - (b) Registered Students and their Supervisor must ensure that required regulatory or ethics review applications are submitted, that their research does not start until the required reviews and approvals are in place, and that the research they undertake is as has been approved. The Supervisor has primary responsibility for ensuring that the student understands the requirements of ethical review appropriate to their research, and that correct processes are followed, but Registered Students remain responsible for their research and for acting as directed by their Supervisor or University officials.
  - (c) Except where there is a regulatory requirement for external review (e.g. research in the NHS, or using relevant material under the Human Tissue Act), Registered Students' research should be reviewed through the appropriate University process.
  - (d) Registered Students who are on undergraduate or postgraduate taught (PGT) courses must seek ethics review via the local systems existing within their School or College. Further information about this should be sought from the School or College Director of Research or Programme Lead.
  - (e) Academic supervisors of Registered Students who are registered on postgraduate research (PGR) courses (e.g. PhD, MRES) must seek review via the central University ethics review process.

- (f) Any Registered Student's research involving animals must comply with University policies on animal research (see clause **9** below).
- 8.5 All animal research engaged in by Researchers must be notified to the Director of the Biomedical Services Unit and reviewed by the appropriate committee as described in clause 9 below.
- 8.6 Where research does not involve people, their data or biological samples, presents no significant risks, does not involve animals or confidential information of third parties and the funder does not require it, it may be appropriate and sufficient for the Principal Investigator to review the ethics of the project.
  - In these circumstances, Principal Investigators must report to the appropriate University Research Ethics Committee that no independent ethical review is required, but they may still request a review from the appropriate University's Research Ethics Committee if they feel that it would be beneficial, and should do so where, in their view, a project raises material ethical issues. Instructions on how to do this can be found here.
- 8.7 No research project (or activity within a research project) may be conducted unless and until the project (or that activity) has been granted a favourable ethics opinion by the appropriate body or person. Failure to obtain a favourable ethics review from the appropriate review body or person, or any breach of the conditions of the ethics decision will be deemed a breach of this Code and dealt with in accordance with the procedure outlined in clause 13 below.
- 8.8 Research must be conducted as described in the application for ethics review, and as granted a favourable ethics review by the relevant ethics committee. Researchers should not deviate in any substantive way from the details of the project as stated in the application (either the initial application or subsequent amendments) which has been granted a favourable ethical approval by the relevant ethics committee, except where necessary to eliminate an immediate hazard(s) to participants.
- 8.9 Research in NHS and Social Care contexts:
  - (a) In addition to ethical review, Researchers conducting research within the remit of the UK Policy Framework for Health and Social Care or the Medicines for Human Use (Clinical Trials) Regulations must obtain the necessary regulatory authorisations and approvals from the appropriate bodies set up for this purpose and must comply with all applicable requirements including the principles of Good Clinical Practice.
  - (b) Where research involves NHS patients, patient data, patient records or patient tissue, or where otherwise required by law (e.g. because of the involvement of 'relevant material' as defined in the Human Tissue Act even if sourced from healthy volunteers or commercial services, or because the research involves adults without the mental capacity to give informed consent), research will require formal Sponsorship, a favourable ethical opinion from a NHS REC and in most cases approval from the Health Research Authority. Information about arranging for Sponsorship of research by the University of Birmingham is available <a href="here">here</a>.
  - (c) Where activity is not classified as 'Research' by the NHS but may still result in research publications or degree theses (e.g. where a piece of work is classified as 'service evaluation' or 'audit' by the NHS) or where NHS research will not be reviewed by a NHS REC, it should be submitted for review through the University's research ethics review process.

If there are other regulatory or legislative requirements for ethics review via a particular channel, these must be met. For example, research involving human participants which is undertaken, funded or sponsored by the Ministry of Defence, requires a favourable ethics opinion/approval from MODREC.

8.11 Advice on procedures for obtaining University ethical review may be obtained from the Research Ethics Team (email <a href="mailto:ethics-queries@contacts.bham.ac.uk">ethics-queries@contacts.bham.ac.uk</a>) and advice on NHS governance approvals or requirements may be obtained from the Research Governance Team (email researchgovernance@contacts.bham.ac.uk).

## 9. Research involving animals

9.1 The University uses animals in biomedical research programmes only where replacement alternatives are not available and where such work is fundamental to advances in understanding that will prevent suffering, protect and prolong human and/or animal life and help preserve animals in their natural environment. It is committed to the development of techniques not involving animals wherever possible.

The University takes its responsibility towards the animals it needs for research seriously. The University promotes the highest standards of animal care, husbandry and welfare, under close veterinary supervision. It has a first class unit with the most up to date equipment available and animals are cared for by a team of highly skilled and dedicated individuals.

- 9.2 The University promotes the use of the <u>ARRIVE guidelines</u> in publications.
- 9.3 Researchers undertaking animal research must hold a personal licence from the Home Office and ensure that there is a Home Office project licence in place covering all procedures that they undertake. Such research must be ethically reviewed by the local AWERB on behalf of the establishment licence holder. Review by the local AWERB ensures that there are no possible alternatives to the use of animals and that studies are carried out to the highest standards of welfare and care, following the 3Rs principle of "replacement", "reduction" and "refinement". The 3Rs are a widely accepted ethical framework for conducting scientific experiments using animals humanely.

All Researchers undertaking research involving animals must comply with the terms of the Home Office Licence upon which they are relying to undertake the research; whether it be their own personal licence or otherwise.

- 9.4 Research involving animals which falls outside of the Animals (Scientific Procedures) Act 1986 (e.g. research involving animals or methods not covered by the act, or taking place outside of the UK) must still be reviewed by the AWERB in order to ensure that the highest standards of welfare and care are applied.
- 9.5 The Director of the Biomedical Services Unit (BMSU), acting on behalf of the Establishment Licence Holder (or named persons under the Establishment Licence in their absence) and named person responsible for compliance, has the authority and power to ensure compliance within the terms and conditions of the Establishment Licence and adherence to the Animal (Scientific Procedures) Act 1986. This includes, but is not limited to, authority, in consultation with the named Veterinary Surgeon, to:
  - (a) bring projects (or planned projects) to the attention of the AWERB. In such cases, Home Office licensees (or potential licensees) for the project (or planned project) will have the opportunity to make a submission to the AWERB; and/or

- (b) suspend or stop activities being carried out by Researchers due to concerns about their compliance with relevant internal or external policies, codes or legislation regarding research and /or animal welfare.
- 9.6 Any potential breaches of Home Office licensing or non-compliance reporting are rapidly responded to and managed in a professional and proactive manner, made possible by the effective working particularly between the University Director of BMSU, Academic Lead for BMSU and the relevant Home Office Inspector (HOI). Timely and constructive dialogue with and response by relevant Heads of School (in consultation with their Head of College and Head of HR, as appropriate), and their conduct of an appropriate academic line management response e.g. appropriate management conversation, through to disciplinary action, is vital to effective consideration and conclusion of such incidents. Reporting of any Home Office licence infringement or non-compliance will be done in accordance with the guidance note held in BMSU titled "Guidance Note: Potential Home Office License Infringement/Non-Compliance Reporting Procedures".
- 9.7 The University is committed to the provision of the appropriate training in order to ensure that any research involving animals is of the highest quality and the welfare of the animals is paramount at all times.

#### 10. Export Controls

- 10.1 Export Control legislation aims to restrict the transfer and communication of sensitive technology, know how and strategic goods to prevent the proliferation of weapons of mass destruction and counter international threats, including terrorism.
- 10.2 Export Control legislation applies to research produced by universities due to the potential for certain research to have a 'dual use'. This means that whilst research may have been developed with a certain purpose in mind, it has the potential to be utilised for other means, including military purposes, weaponry/arms, weapons of mass destruction, and terrorism.
- 10.3 Details on UK, EU, and USA Export Control legislation can be accessed via the University's dedicated Export Control webpages
- 10.4 The responsibility for compliance with Export Control legislation ultimately rests with the individual researcher or staff member who intends to export goods, technology, software, or knowledge outside of the UK, or use technology imported from the United States of America. Any researcher who believes that Export Control legislation may apply to their research (and/or the research of any PhD students who they supervise), must contact the RSSD via export-control@contacts.bham.ac.uk prior to the commencement of the research, and must contact Birmingham Global via <a href="mailto:a.m.chambers@bham.ac.uk">a.m.chambers@bham.ac.uk</a> prior to any planned international travel related to the research, to receive advice with regards to compliance with Export Control legislation. All PhD programmes and projects must also be compliant with Export Control legislation, and any Supervisor who believes that there may be Export Control concerns must contact the University Graduate School via graduateschool@contacts.bham.ac.uk
- 10.5 A flowchart outlining the key steps that Researchers should follow to ensure compliance with Export Control legislation is available on the University's Export Control intranet pages. Compliance with Export Control legislation is the responsibility of the individual researcher, with criminal sanctions applying to wilful breach of the legislation. Any Researcher who is unsure as to whether their research as Export Control considerations should contact the RSSD via export-control@contacts.bham.ac.uk prior to transferring any knowledge to any international organisations.

## 11. Security-sensitive research material

- 11.1 Under the Counter-Terrorism and Security Act 2015, the University is under a duty to have due regard to the need to prevent people being drawn into terrorism. In doing so, it must have particular regard to its duty to take all reasonable steps to ensure freedom of speech and to protect academic freedom.
- 11.2 In order to help protect Researchers (and the University) against possible misinterpretation of their research activity, all Researchers undertaking research involving potentially security-sensitive research material must comply with <u>guidance</u> <u>issued by the University</u>, as amended from time to time, concerning (but not limited to):
  - (a) accessing security-sensitive websites;
  - (b) storage of security-sensitive material; and
  - (c) notification of suspected terrorist activity or contact with extremist ideologies.
- 11.3 Researchers should also comply with the University's <u>General Conditions of Use of Computing and Network Facilities</u>, including but not limited to the guidance it contains on the storage of sensitive material.
- 11.4 Cyber security research must comply with the Code of Practice for Cyber Security Research, and, in particular, where a security vulnerability is identified Researchers must follow the prescribed disclosure process.

## 12. Adverse Events

- 12.1 An "Adverse Event" is an event which results in or may result in harm or damage to the interests the Researcher, the research participants, the University (including its reputation), society, the environment or in a failure to maintain appropriate standards of animal welfare. Researchers have a duty to monitor and report any Adverse Events occurring in the course of the research to appropriate committees e.g. for studies reviewed via the University Research Ethics Committee to Committee Chairs. Clinical Trials must follow <a href="UoB Quality Management System">UoB Quality Management System</a> requirements. Each College must have systems in place to ensure that all such Adverse Events are recorded and, if appropriate, investigated.
- 12.2 Accidents, incidents and "near misses" occurring during the course of research should be reported to the School/College Health and Safety Coordinator in accordance with the University's Health and Safety Policy and also to the University's Head of Research Governance and Integrity. GDPR and DPA breaches, including near misses, should be referred to the University's Legal Services department immediately.
- 12.3 Researchers should be aware that there may be a legal or regulatory requirement for them to report Adverse Events directly to external bodies, such as the National Research Ethics Service committees, the Competent Authority or collaborating partners and insurers, within specified timeframes. Researchers have a duty to be aware of these requirements and ensure that all such adverse events are reported appropriately.

#### 13. Misconduct in research

13.1 Misconduct in research is a failure to comply with the provisions of this Code and includes, but is not limited to, the following conduct:

- (a) Fabrication, including the creation of false data or other aspects of research, including research documentation such as regulatory or internal approvals or participant consents.
- (b) Falsification of data or results, including, but not limited to:
  - falsification and/or inappropriate manipulation and/or selection of consents and
  - falsification and/or inappropriate manipulation and/or selection of data/imagery.

## (c) Plagiarism, including:

- the wrongful appropriation or purloining and publication as one's own, of the thoughts, ideas or the expression of ideas (literary, artistic, musical, mechanical, etc.) of another:
- the exploitation of the ideas, work or research data of others without proper acknowledgement, whether intentional or not; and
- poor referencing of the work of others, whether through carelessness or negligence.

## (d) Misrepresentation, including:

- falsely or unfairly presenting the ideas or the work (including data) of others as one's own, whether or not for personal gain or enhancement, including both by deliberate misstatement or as a result of negligent or inadequate reference;
- misrepresentation of data, for example, suppression of relevant findings with intention to deceive and/or knowingly, recklessly or by gross negligence presenting a flawed interpretation of data;
- misleading ascription of authorship in a publication;
- undisclosed duplication of publication, including undisclosed simultaneous duplicate submission of manuscripts for publication;
- deliberately attempting to deceive when making a research proposal;
- misrepresentation of skills, qualifications and/or experience, including claiming or implying possession of skills, qualifications or experience which are not held;
- misrepresentation of interests, including failure to declare material interests either of the Researcher or of the Funders of the research; or
- misrepresentation of the status of a research project, the associated approvals
  or its conduct knowingly, recklessly, or through negligence.
- (e) Mismanagement of data and/or primary source materials, including failure by those identified under clause 3 (above) as having relevant roles and responsibilities to:

- keep clear and accurate records of the research procedures followed and the results obtained, including interim reports;
- hold records securely in paper or electronic form;
- make relevant primary data and research evidence accessible to others for the required period after completion of the research; or
- manage data according to the <u>University's Research Data Management Policy</u> or any data policy of a research Funder (as appropriate) and all relevant legislation.
- (f) Breach of any relevant duty of care, which may involve recklessly or through negligence:
  - failing to follow procedures and health and safety protocols which are designed to prevent unreasonable risk or harm to humans, animals or the environment;
  - breaching the confidentiality of individuals or groups involved in research whether Researchers or research subjects without their consent, including, for example, improper disclosure of the identity of individuals or groups;
  - placing any of those involved in research in physical danger, whether as Researchers, research subjects, participants, or associated individuals, without their prior consent, and without appropriate safeguards where informed consent is given;
  - not taking all reasonable care to ensure that the risks and dangers, the broad objectives, and the Sponsors and Funders of research are made known to participants or their legal representatives in order to ensure that appropriate informed consent is obtained properly, explicitly and transparently;
  - failing to obtain appropriate informed consent where permission to conduct research without appropriate informed consent has not been obtained from the relevant University or external research ethics committee;
  - failure to obtain a favourable ethical opinion or approval from the appropriate review body or person, or any breach of the conditions of the ethics opinion or approval;
  - failure to follow a reasonable instruction in relation to research by the relevant budget holder, the Director of Research and Knowledge Transfer for the relevant College, or otherwise appropriately authorised member of staff;
  - failing to produce the Essential Documents for a study conducted under the UK Framework for Health and Social Care Research upon request;
  - unethical behaviour in the conduct of research;
  - failing to comply with any requirements or stipulations contained in ethics opinions, conditions, approvals or regulatory authorisations or deviating in a substantial way from the described research for which regulatory authorisation or Research Ethics Committee favourable ethical opinion or approval (including approval from University of Birmingham Research Ethics Committees) was obtained;

- conducting research on animals without the appropriate approval from
- the AWERB and home office licences, or failing to meet the conditions of the applicable home office licences and AWERB approval;
- conducting regulated research without gaining the required regulatory approvals, including but not limited to conducting a regulated clinical trial without authorisation of the relevant Competent Authority.
- failing to comply with any legal requirements or protocols set out in the guidelines of appropriate, recognised professional, academic, scientific and governmental bodies:
- failing to conduct clinical research in accordance with the University's quality management systems as outlined in the <u>Research Quality Manual</u>.
- failure to include the details of research outputs in the relevant University research publications databases according to the relevant procedures for recording that information and/or failure to ensure wide dissemination of publications by including outputs in a publicly accessible repository;
- unauthorised use of information acquired confidentially, or
- conducting research which in its design, conception or conduct breaks the law or otherwise jeopardises the reputation of the University.

## (g) General Misconduct, including:

- the misuse of research findings;
- failure to declare an actual or potential conflict of interest which may significantly compromise, or appear to significantly compromise, the research integrity of the individual concerned and the accuracy of any research findings or bring the University into disrepute;
- inciting others to commit research misconduct;
- failure to declare (where known) that you have or a collaborative partner has been found to have committed research misconduct in the past or is currently being investigated following an allegation of research misconduct. Such declarations should be made to the Head of College and to the Head of Research Governance and Ethics;
- facilitating misconduct in research by collusion in, or concealment of, such action;
- breach of University or externally contracted confidentiality, except where part of genuine whistle-blowing actions in accordance with the Public Interest Disclosure Act 1998;
- fraud, including financial fraud; or
- any misconduct which would normally be regarded as a disciplinary matter if conducted on University premises, which is committed whilst working on a collaborating institution's premises or other off-campus facility or research site,

whilst conducting a University or collaborative research project, secondment, or industrial placement.

- 13.2 Researchers and other members of Staff have a duty to report any potential breach of this Code where they have good reason to believe it is occurring to the Head of College, the College Director of Research and Knowledge Transfer, the Head of School or the Head of Research Governance and Integrity. The procedures and protections set out in the <a href="University's Code of Practice on Corporate Governance">University's Code of Practice on Corporate Governance</a> in relation to Public Interest Disclosure ('Whistle blowing') shall apply as appropriate in the area of the conduct of research.
- 13.3 The University may, if it deems appropriate, report suspected research misconduct to relevant regulatory bodies, professional bodies and/or Funders prior to any formal allegation, investigation or official finding of research misconduct.
- 13.4 In accordance with clause 13.2, the person to whom research misconduct is reported will notify the Head of College and the HR Director (or the Assistant Director of HR Operations), if relating to a member of staff, or the Academic Registrar (or nominee), if relating to a Registered Student, and the Head of Research Governance and Integrity of the allegation. The HR Director or Assistant Director of HR Operations will in turn brief the PVC, Research and Knowledge Transfer and the Director of Legal Services (or their nominee). The Head of Research Governance and Integrity will keep a record of all allegations reported to them.
- 13.5 Where an alleged breach is reported under clause 13.2, the Head of College (or a nominee) may decide to undertake a review into the allegations ("the Management Review") and will produce a written report of their findings. Where a nominee is appointed to report under the Management Review, they will be a senior academic (which may be an Emeritus Professor or senior academic from another University) with relevant knowledge of the area of research that is subject to the Management Review. Where appropriate, the decision as to who to appoint to undertake the Management Review will be taken in conjunction with the PVC, Research and Knowledge Transfer and the Director of Legal Services (or their nominee) where appropriate. Alternatively the Head of College may decide that the factual basis of the allegation is clear, and the matter warrants a formal disciplinary investigation. In which case the Head of College will report the matter to HR in accordance with clause 13.8.
- 13.6 The Head of College will be responsible for ensuring that the PVC, Research and Knowledge Transfer, HR, Head of Research Governance and Integrity and Legal Services are kept up-to-date as to the progress and outcome of the Management Review (if any).
- 13.7 Where appropriate the Head of College may determine that guidance or comment should be sought from an external expert as part of the Management Review or on its findings.
- 13.8 Where the Management Review indicates that there is a sufficient factual basis to warrant a formal disciplinary investigation then the relevant investigation and disciplinary process will be instigated in relation to the Researcher (or Researchers) in accordance with the University's Ordinances and Regulations in respect of Academic Staff and Registered Students and in accordance with appropriate terms and conditions of employment for all other staff.
- 13.9 Where the Management Review concludes that there is a factual basis for the allegations, but the conduct is not so serious as to warrant the instigation of a formal disciplinary process, then the University may take such other measures as are provided for within this Code, including (but not limited to) those detailed in clause 13.13. Where the Management Review considers there is no case to answer, the Head of College will notify HR or the

Student Conduct Office and/or the College Fitness to Practice team so that the record of the allegation is amended accordingly.

- 13.10The University considers an accusation of research misconduct to be within its remit and suitable for consideration under clause 13.5 of this Code and, where appropriate, according to its relevant disciplinary procedures if it is alleged to have been committed (in whole or in part) by:
  - (a) a member of Staff, Honorary Staff, Emeritus Professor or Registered Student;
  - (b) a Visiting Researcher who is recognised as such by the University;
  - (c) a member of Staff or Honorary Staff, whether or not it is alleged to have occurred at a location external to the University;
  - (d) a former member of staff or former Registered Student if the research was undertaken at the University or on the University's behalf;
  - (e) Registered Students on Leave of Absence;
  - (f) External Students; or
  - (g) Graduands and students with Thesis Awaited status.
- 13.11 The University reserves the right to conduct a Management Review or other investigation (or conclude a Management Review or other investigation) where the Researcher concerned leaves, or has left, the University.
- 13.12An allegation of research misconduct is a serious and potentially defamatory action and could lead to a threat, or even the instigation, of legal proceedings. Consequently, for the protection of complainants who make allegations in good faith and of the parties against whom the allegations are made, all enquiries, including the formal investigation (if any), should be conducted with discretion and on a confidential basis where possible. Appropriate consideration will be given to the level of disclosure by the Pro Vice Chancellor Research and Knowledge Transfer, particularly where there may be an expectation of disclosure to a regulatory body such as the Funder, the General Medical Council, UKRI or the Office for Students.
- 13.13At any point after an alleged breach is reported under clause 13.2, it may be necessary to consider additional measures. Such additional measures will be determined by the relevant Head of College and the Pro-Vice Chancellor Research and Knowledge Transfer and might include, but are not limited to:
  - (a) retraction/correction of articles in journals or other published material;
  - (b) withdrawal/repayment of funding;
  - (c) notification of misconduct to regulatory bodies;
  - (d) notification of other employing institutions/organisations:
  - (e) notification of other organisations involved in the research including the Funders of the research;
  - (f) review of internal management and/or training and/or supervisory arrangements;

- (g) making any public statement necessary to protect the good name and reputation of the University; or
- (h) revocation of any degree awarded on the basis of the affected research.
- 13.14The <a href="RCUK Policy and Guidelines">RCUK Policy and Guidelines on the Governance of Good Research Conduct</a> and UKRI requires that funders are notified of allegations of unacceptable research conduct. Where serious misconduct is found to have occurred, especially where this would appear to have been premeditated, a report to relevant statutory or regulatory bodies may be required.
- 13.15The University retains the right to report proven allegations of serious research misconduct against its Staff, Honorary Staff, former Staff and Registered Students and former Registered Students, to potential new and subsequent employers. Where employees or students of another institution involved in a collaborative project with the University are implicated in a University finding of serious research misconduct, then the University shall notify the home institution of those individuals involved.
- 13.16The identity of any individual reporting research misconduct, where it is genuinely suspected, will be kept confidential wherever practicable. However, the University may reveal the identity of the individual reporting misconduct if this is deemed necessary to allow the person accused of misconduct to conduct their defence.
- 13.17Where there is prima facie evidence that an allegation of research misconduct is founded on vexatious or malicious intent, this may be considered as a disciplinary matter.
- 13.18Where an allegation of research misconduct against a member of staff or Registered Student is found by the University to be vexatious or without foundation, the University will take reasonable action to support researchers in responding to the claim and take appropriate steps to protect their, and the University's, reputation.
- 13.19All new members of Staff, including Honorary Staff, will be required to sign a declaration stating that they have not been found to have committed serious research misconduct (i.e. warranting at least a formal written warning) prior to their appointment and are not currently under investigation at another institution following an accusation of research misconduct.