Introduction

This 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 Code of Ethics, 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.

This code of practice reiterates the commitment to academic freedom 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 ethics and governance processes managed by specialist committees which report into the Research Governance Ethics and Integrity Committee. Researchers affected by these requirements should contact the Research Governance and Ethics Team for support in the first instance.

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

This Code also covers the following areas:

- Management of research data (Section 4, p.10).
- Assignment of intellectual property (Section 6, p.14)
- Conflicts of interest (Section 7, p.15)
- Research involving controlled items (Section 10 p.20)

This document should be read in conjunction with the relevant Conditions of Employment, University Ordinances and Regulations, the University’s Codes of
Practice (including but not limited to the Code of Ethics), 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

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
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<tr>
<td>Adverse Event</td>
<td>See definition at paragraph 12.1 below.</td>
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<tr>
<td>AWERB</td>
<td>Animal Welfare and Ethical Review Body</td>
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<td>BMSU</td>
<td>Biomedical Services Unit</td>
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<td>Chief Investigator (applies to medical research)</td>
<td>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.</td>
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<tr>
<td>Citation Clubs</td>
<td>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.</td>
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| 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. |
<p>| this 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 licences 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 |
| CTOC | The Clinical Trials Oversight Committee |
| UK Policy Framework for | UK Policy Framework for Health and Social Care (as amended from time to time). |</p>
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<tr>
<th>Health and Social Care</th>
<th>The Data Protection Act 2018 (as subsequently amended).</th>
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<tr>
<td>Emeritus Professor</td>
<td>A Professor of the University on whom the title of “Emeritus Professor” has been conferred on or after his retirement.</td>
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<tr>
<td>Essential Documents</td>
<td>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, Sponsor and monitor with standards of Good Clinical Practice (where applicable) and with all applicable regulatory requirements.</td>
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<tr>
<td>Establishment Licence</td>
<td>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.</td>
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<tr>
<td>Establishment Licence Holder</td>
<td>The holder of the University’s Establishment Licence as issued by the Home Office.</td>
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<tr>
<td>Funder</td>
<td>The individual(s) or organisation(s) which pays wholly or partially for the conduct of a research project.</td>
</tr>
<tr>
<td>Good Clinical Practice</td>
<td>An international scientific quality standard for the design, conduct, monitoring, auditing, recording, analyses and reporting of Clinical Trials.</td>
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<tr>
<td>Intellectual Property Rights</td>
<td>All intellectual property rights throughout the world for the full term of the rights concerned and including all extensions and renewals of such rights, whether or not such rights are registered or capable of registration, including, without limitation, copyright, database rights, patents, rights in inventions, know-how and technical information, design rights, registered designs, trade marks (including business and brand names, domain names, devices and logos) and the right to apply for any of the foregoing anywhere in the world.</td>
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<tr>
<td>Management Review</td>
<td>See paragraph 13.5 below.</td>
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<td>Misconduct</td>
<td>See paragraph 13.1 below.</td>
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<td>NHS REC</td>
<td>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.</td>
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<td>Principal Investigator</td>
<td>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</td>
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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 organization 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.

UKRI
UK Research and Innovation

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; and
- 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.

RSS
Research Support Services department at the University

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
Means 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.

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 is 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).

Registered Students are responsible and accountable for their own conduct and for abiding by the guidance provided by their supervisors and this Code.

2.6. The University’s Research Committee will review the Code on an annual basis, in consultation as appropriate with relevant individuals or groups. The review will take into account the Code’s implementation, changes and recommendations from external research Funders, Regulators, Acts of Parliament and other regulations.

2.7. 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.

2.8. 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. 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.

3.2. 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.

3.3. The Principal Investigator in 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.

3.4. The Principal Investigator is accountable for the duties and responsibilities set out below (note that this is not an exhaustive list of duties):

(i) the necessary ethical basis of the research and the research design;

(ii) the safety of all involved in the research;

(iii) the suitability of the working environment and adequate provision of equipment and facilities;
(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) use of reasonable endeavours to ensure the observance of University and third-party Intellectual Property Rights;

(ix) management of research data in accordance with the GDPR, the DPA and any other external or internal legislative provision, 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 and make documents relating to a research project available to internal and external auditors /monitors and regulatory bodies;

(x) timely and appropriate dissemination of research findings;

(xi) 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;

(xii) maintenance of personal records of research progress, including authorised laboratory books, to the recommended or required standards;

(xiii) maintaining confidentiality in order to achieve protection of Intellectual Property Rights, commercially sensitive data, personal data and other confidential information where appropriate;

(xiv) 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;

(xv) 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;

(xvi) awareness of the ways in which research derives from and affects the work of others, and respecting the rights and reputation of others;

(xvii) 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;
(xviii) ensuring the adequate provision of appropriate facilities, resources, expertise, and any necessary protection, for example insurance, prior to the commencement of the research;

(xix) for applicable clinical research, compliance with the University’s Quality Management Systems outlined in the University’s Research Quality Manual (accessible via the Clinical Research Quality Management Systems web page). The categories of work to which this applies are detailed within the Research Quality Manual;

(xx) recording of research methods and data in a way that allows for independent verification of the integrity of the research process and outputs.

Each of these duties may be delegated to appropriate persons, but the Principal Investigator must retain oversight and remains accountable. Researchers have a responsibility to carry out their research in accordance with any reasonable instructions given by the Principal Investigator in the exercise of his/her duties.

3.5. Where a Researcher (including the Principal Investigator) has concerns about whether the obligations of accountability as set out in paragraph 3.3 (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 then advice should be sought from the Research Development Manager in the College in the first instance. A Registered Student who has any questions about this Code should in the first instance raise these with their Supervisor.

3.6. 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:

3.6.1. Researchers undertaking research funded by the UK Research and Innovation must abide by the UKRI’s principles, policy and guidelines for good research conduct

3.6.2. Researchers undertaking research funded by the EU under Horizon 2020 must comply with the ethical standards and guidelines of Horizon 2020 (see Horizon 2020 online manual) and the ethical principles and relevant national, EU and international legislation, for example the Charter of Fundamental Rights of the European Union and the European Convention on Human Rights.

3.7. Funding received by the University from the 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.
3.8. Where research funding award has been classified by the funder as overseas development aid (for example, funding awarded under the Global Challenges Research Fund), the University is required to undertake additional due diligence checks on the global partners collaborating in the research. The PI will also need to put in place appropriate project oversight and governance to ensure the appropriate use of grant funding flowing to partners. For further information and guidance, see: Due Diligence for Research with Global Partners web page.

3.9. Funder requirements should not be allowed to adversely affect the standard of research conducted or unduly influence research outcomes and outputs.

4. Research Data

4.1. Researchers must comply with the University's Policy on Research Data Management, which provides more detailed guidance on this matter and definitions of Research Data and Open Data.

The University policy is accessible via the Research Data Management Policy web page.

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 followed 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 Legal Services intranet page and advice may be obtained from Legal Services.

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 remains the property of the University when a researcher leaves. Where research data has been made open on conclusion of a project, the researcher in question may access it in the normal manner; if not, an access request will be required.

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.
5. Publications

5.1 Publication is the dissemination of the outcomes of research in paper form and/or in other media, including electronic media. Publication may be taken to include, inter alia, books, chapters, articles, conference proceedings, reviews, patents, catalogues, compositions, the production of creative arts, theses, software, databases, museum exhibitions, web-sites, e-bulletins, press releases, media briefings or other events. The University encourages its Researchers to disseminate the findings of their research through appropriate and timely publication.

5.2 Ethical considerations apply to the production of all categories of publication. 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 below and the University’s statement on research publications.

5.3 All Researchers are required to include the details of their research outputs in the relevant University research publications databases according to the relevant procedures for recording that information. Further information about Pure, the University’s research information management system, can be found at the University’s Pure – Research Information System web page. All Researchers must ensure wide dissemination of their publications by including their outputs in a publicly accessible repository in line with the University’s statement on research publications. Researchers should ensure that they comply with the open access mandate of Research England and other Funders. Advice can be obtained from Library Services (email openaccesspublications@contacts.bham.ac.uk) or the Planning Office.

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 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 which 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 Plagiarism information for staff intranet page and the Plagiarism intranet page).

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).

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 than Researchers are required to retract or correct any of their publications reporting or based on those data.

6. Intellectual Property

6.1 The University will own the Intellectual Property Rights arising from research undertaken by 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), unless a prior contractual arrangement assigns such rights to a Sponsor or Funder.
In the case of external research collaborators, the collaboration agreement will set out the ownership of Intellectual Property Rights.

6.2. Registered Students who, in the course of their study or research, develop intellectual property with material input from the University’s academic staff or as part of a collective project, programme or research activity, must make assignment of all rights in such intellectual property to the University. See Regulation: Admission and Registration (Section 5.4 Intellectual Property) for full details.

6.3. The University does not in practice assert its ownership of the copyright in respect of material such as books, journal articles, and musical compositions where there is no substantial commercial interest. However, the University retains its right to use and reproduce such materials for its educational and research purposes, including hosting in an online repository, whilst recognising the author’s moral rights to be identified as the author or creator of the work.

6.4. 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:

- University Regulation 3.16
- Regulation 5.4
- Registered Students involved in research are expected to comply with the requirements of Regulation 3.16.
- Appendix 6 of the Conditions of Employment Governing Academic and Academic-related Staff

6.5. Where an invention or discovery with potential commercial significance has been made in the course of research, Researchers are required to make appropriate notification to the Head of College as set out in Regulation 3.16 or Regulation 5.4.

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 (info@enterprise.bham.ac.uk, telephone 0121 414 9090), the wholly owned subsidiary of the University with sole responsibility for the exploitation of the University IP. Breaches of confidentiality may result in actions for recovery of losses from a Funder against the University and the individual concerned. 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 relating to externally funded or collaborative research may result in actions for recovery of losses from a Funder against the University and the individual concerned.

6.6. Researchers who leave the University are reminded that 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.

6.7. All publications, reports and other material issued by Researchers should bear an appropriate assertion of authorship and a copyright statement.

6.8. When peer reviewing research proposals or results (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 must not misuse or misappropriate the content of the material being reviewed.

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 him/herself 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 Protocol on Conflicts of Interest and the Bribery Act Policy.

Failure to declare known conflicts of interest may be deemed misconduct.

7.2. A Researcher 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 self-assess proposed research and ensure that it is submitted to the correct review process.

8.2. University Ethics Review

8.2.1. University ethics review processes must be used for research involving people or their data that does not require NHS (or other mandatory) ethics committee review.

8.2.2. The processes provide a robust review of research led by Staff and Registered Students who are registered on postgraduate research programmes, 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 Governance and
Ethics team, before seeking any appropriate ethics review as required (via the initial project registration form).

8.3. An appropriate ethics review independent of the research team and completion of study appropriate due diligence processes is required for all University research where:

8.3.1. 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;

8.3.2. The research presents a significant risk to the environment, society or the reputation of the University;

8.3.3. 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;

8.3.4. The research presents other material ethical concerns.

8.4. 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.

8.5. 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.

8.6. 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 dealt with in accordance with the procedure outlined in clause 13 below and will be deemed a breach of this Code.

8.7. 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.

8.8. Research in NHS and Social Care contexts:

8.8.1. 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.

8.8.2. 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 here.

8.8.3. 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.

8.9. Other regulatory requirements

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.

8.10. Registered Student research

8.10.1. Ethics review is required for any Registered Student’s research project where clauses 8.3.1 to 8.3.4 apply.

8.10.2. For Registered Students, 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.

8.10.3. 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.

8.10.4. 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:

8.10.5. 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.

8.10.6. 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.

8.10.7. Any Registered Student’s research involving animals must comply with University policies on animal research (see clause Error! Reference source not found. below).

8.11. Advice on procedures for obtaining University ethical review may be obtained from the Research Ethics Officer (email ethics-queries@contacts.bham.ac.uk or telephone 0121 414 8825) and advice on NHS governance approvals or requirements may be obtained from the Research Governance Officer (telephone 0121 414 7618 or 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 ARRIVE guidelines 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:

(i) 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

(ii) suspend or stop activities being carried out by Researchers due to concerns about its 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. Research involving Controlled Items

10.1. Export controls apply to the transfer (by any means) of goods, technology, software and/or knowledge from the UK to a destination outside the UK that may have dual use for military purposes or for Weapons of Mass Destruction purposes.

All Researchers undertaking research involving export of Controlled Items (meaning those listed on the UK Strategic Export Control Lists must ensure that an appropriate export licence is obtained and must comply with the licensing conditions and any other applicable legal requirements.

Guidance has been issued by Project Alpha at Kings College London and the Association of University Legal Practitioners on export control for academia.

The University contact for SPIRE (the online export licensing system for the Export Control Office) is Dr Ian Lyne, Director of Research Support Services.

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 guidance issued by the University, as amended from time to time, concerning (but not limited to):

(i) accessing security-sensitive websites; and
(ii) storage of security-sensitive material.
(iii) notification of suspected terrorist activity or contact with extremist ideologies.

11.3. Researchers should also comply with the University’s General Conditions of Use of Computing and Network Facilities, 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 a failure to maintain appropriate standards of animal welfare. Researchers have a duty to monitor and report to the Head of Research Governance and Integrity and, if relating to a clinical trial, the CTOC, any Adverse Events occurring in the course of the research. 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 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 collaborative 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

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:

13.1.1. Fabrication, including the creation of false data or other aspects of research (including research documentation such as regulatory or internal approvals or participant consents).

13.1.2. Falsification of data or results, including (but not limited to):

(i) falsification and/or inappropriate manipulation and/or selection of
consents and
(ii) falsification and/or inappropriate manipulation and/or selection of data/imagery.

13.1.3. Plagiarism, including:

(i) 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;

(ii) the exploitation of the ideas, work or research data of others without proper acknowledgement, whether intentional or not; and

(iii) poor referencing of the work of others, whether through carelessness or negligence.

13.1.4. Misrepresentation, including:

(i) 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;

(ii) 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;

(iii) misleading ascription of authorship to a publication;

(iv) undisclosed duplication of publication, including undisclosed simultaneous duplicate submission of manuscripts for publication;

(v) deliberately attempting to deceive when making a research proposal;

(vi) misrepresentation of skills, qualifications and/or experience, including claiming or implying skills, qualifications or experience which are not held;

(vii) misrepresentation of interests, including failure to declare material interests either of the Researcher or of the Funders of the research; or

(viii) misrepresentation of the status of a research project, the associated approvals or its conduct knowingly, recklessly, or by gross negligence.

13.1.5. Mismanagement of data and/or primary source materials, including failure by those identified under 3 as having relevant roles and responsibilities to:

(i) keep clear and accurate records of the research procedures followed and the results obtained, including interim reports;

(ii) hold records securely in paper or electronic form;

(iii) 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 University’s Research Data Management Policy or any data policy of a research Funder (as appropriate) and all relevant legislation.

13.1.6. Breach of any relevant duty of care, which may involve recklessly or through negligence:

(i) failing to follow procedures and health and safety protocols which are designed to prevent unreasonable risk or harm to humans, animals or the environment;

(ii) 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;

(iii) 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;

(iv) 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;

(v) 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;

(vi) 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;

(vii) 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;

(viii) failing to produce the Essential Documents for a study conducted under the UK Framework for Health and Social Care Research upon request;

(ix) unethical behaviour in the conduct of research;

(x) 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;

(xi) 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;

(xii) 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.

(xiii) failing to comply with any legal requirements or protocols set out in the guidelines of appropriate, recognised professional, academic, scientific and governmental bodies;

(xiv) failing to conduct clinical research in accordance with the University’s quality management systems as outlined in the Research Quality Manual.

(xv) 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;

(xvi) unauthorised use of information acquired confidentially, or

(xvii) Conducting research which in its design, conception or conduct breaks the law or otherwise jeopardises the reputation of the University.

13.1.7. General Misconduct, including:

(i) the misuse of research findings;

(ii) 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;

(iii) inciting others to commit research misconduct;

(iv) 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;

(v) facilitating misconduct in research by collusion in, or concealment of, such action;

(vi) breach of University or externally contracted confidentiality, except where part of genuine whistle-blowing actions in accordance with the Public Interest Disclosure Act 1998;

(vii) fraud, including financial fraud; or

(viii) 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
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 University’s Code of Corporate Governance 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 at 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.

13.10. The University considers an accusation of research misconduct to be within its remit and suitable for consideration under clause 13.4 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:

(i) a member of Staff, Honorary Staff, Emeritus Professor or Registered Student;

(ii) a Visiting Researcher who is recognised as such by the University;

(iii) a member of Staff or Honorary Staff, whether or not it is alleged to have occurred at a location external to the University;

(iv) a former member of staff or former Registered Student if the research was undertaken at the University or on the University’s behalf;

(v) Registered Students on Leave of Absence;

(vi) External Students; or

(vii) 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.

13.12. An 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 the complainant (who makes an allegation in good faith) and of the party 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 GMC, UKRI, or OfS.

13.13. At 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):

(i) retraction/correction of articles in journals or other published material;

(ii) withdrawal/repayment of funding;

(iii) notification of misconduct to regulatory bodies;

(iv) notification of other employing institutions/organisations;

(v) notification of other organisations involved in the research including the
Funders of the research;

(vi) review of internal management and/or training and/or supervisory arrangements;

(vii) making any public statement necessary to protect the good name and reputation of the University; or

(viii) Revocation of any Degree awarded on the basis of the affected research.

13.14. The RCUK Policy and Guidelines on the Governance of Good Research Conduct 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.

13.15. The 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.

13.16. The identity of any individual reporting research misconduct, where it is genuinely suspected, will be kept confidential wherever practicable. However, it 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.

13.17. Where 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.

13.18. Where 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 safeguard their, and the University’s, reputation.

13.19. All 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.