

Code of Research Conduct and Research Ethics

Foreword by Pro-Vice Chancellor Research and Knowledge Exchange

The University of Nottingham's *Code of Research Conduct and Research Ethics* provides a comprehensive framework for good research conduct and the governance of all research carried out across the University, including the University's international campuses. The Code underpins the University's commitment to maintaining the highest standards of integrity, rigour and excellence in all aspects of our research and for all research to be conducted according to the appropriate ethical, legal and professional frameworks and standards. The Code is a fundamental component of the research environment, which is characterised by our culture of research integrity, good research practice, and the development and training of researchers at all stages of their careers. The Code outlines the duty of researchers including their responsibilities towards all participants of research including humans, animals, the environment and cultural materials, and it provides a basis for the transparent and appropriate communication and dissemination of research findings. The University welcomes the national framework for good research conduct and governance published as the *Concordat to Support Research Integrity* and endorses the Concordat as a recipient of public funding for research. This Code has been reviewed to be consistent with the commitments and aims of the Concordat and is the basis for applying research integrity across the University, including the University's international campuses in China and Malaysia. We will monitor and, where necessary, improve the Code in order to further strengthen the integrity of research carried out across the University.

Professor Dame Jessica Corner
Pro-Vice Chancellor Research and Knowledge Exchange



Foreword by the Chair of the University Research Integrity and Research Ethics Committee

This Code of Research Conduct and Research Ethics has been reviewed and revised in light of feedback from colleagues and to reflect the changes in the ever-evolving research landscape. This Code needs to be a comprehensive document since it covers the wide range of research conducted at the University.

It is essential that all academics and researchers within the University of Nottingham are aware of the contents of this code, to ensure that we maintain the highest standards of integrity, rigour and excellence across our entire research environment.

As part of the recent revisions of the Code I am delighted to include a Brief Summary of the Code of Research Conduct and Research Ethics which highlights aspects of research associated with particular risks or requirements in terms of research ethics, integrity or governance. The Summary signposts sources of additional support and guidance, including within the Code.

All staff and students involved in research are expected to be familiar with the Summary (and to keep up to date with any revisions), to enable them to be aware of situations in which they are likely to need to seek further information, advice or guidance from the full Code.

This Code and its Brief Summary are reviewed annually and updated as necessary by the University Research Integrity and Research Ethics Committee (URIEC).

Professor Penny Gowland
Professor of Physics and Chair of URIEC



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A Brief Summary of The Code of Research Conduct and Research Ethics for the University of Nottingham

All staff and students engaged in research for the University of Nottingham (UoN) are expected to maintain the highest standards in ethics and integrity, and to adhere to all to all applicable statutes and government guidelines, as set out in the [Code of Research Conduct and Research Ethics](#) (the Code). The Code applies to all research activity conducted carried out by UoN staff or students, irrespective of how it is funded or where it is carried out. Guidance and training can be found on the Research Integrity and Ethics [SharePoint pages](#).

The Foundations of Good and Responsible Research Practice

[The Concordat to Support Research Integrity](#) highlights the key principles which provide trust and confidence in research and its outputs;

- honesty
- rigour
- transparency and open communication
- care and respect
- accountability

These apply to all aspects of research, including development of research aims and objectives, preparation of grant and project proposals, acquisition and analysis of data, publication and dissemination of findings, and provision of expert peer review on proposals or publications from others.

As a researcher, you should be able to exercise freedom in your academic choices (see [Free Speech and Academic Freedom at the University of Nottingham](#)), but you must:

- understand what constitutes rigour and integrity in your area of research;
- maintain the highest standards of rigour and integrity in your work at all times;
- comply with legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities, employers, funders and other relevant stakeholders;
- ensure that all research is subject to active and appropriate consideration of ethical issues, including the wider impact of your research (see [Responsible research & innovation](#));
- maintain a research environment that encourages research integrity;
- design, conduct and report research in ways that embed integrity and ethical practice;
- handle potential instances of research misconduct in an appropriate manner, acting in good faith and taking reasonable steps to ensure any recommendations made by formal research misconduct investigation panels are implemented;
- declare and act accordingly to manage conflicts of interest;
- monitor and report any adverse events occurring in the course of your research according to the process in your School (i.e. Ethics Committee, Safety Office, Data Protection Officer etc.).

Research Misconduct

The University seeks to provide a research environment that fosters and supports honesty in research and discourages unacceptable behaviour by dealing seriously and sensitively with all allegations of research misconduct. Examples of research misconduct include fabricating data, misrepresenting data, and failing to meet ethical and legal requirements.

- [University's Code of Practice on Handling Allegations of Research Misconduct](#)

Ethical Considerations

The UoN's core key principles for ethical research apply to all its research:

| | | | | |
|--------------------|-----------------|---------------------|-----------------------------|----------------------------|
| Maximising benefit | Minimising harm | Respecting autonomy | Fairness and accountability | Integrity and transparency |
|--------------------|-----------------|---------------------|-----------------------------|----------------------------|



The Chief/Principal Investigator is responsible for ensuring proper ethical review, but you must ensure that you are fully aware of, and comply with, the University's expectations for the ethical conduct of research, the ethical requirements of research funders, and the expectations of your research discipline and professional bodies. All the ethical implications of a research project must be considered, including the impact on:

- a. anyone involved in or affected by the research;
- b. welfare of animals;
- c. cultural sensitivities;
- d. protected species and sites;
- e. the environment.

Training, Supervision and Management

All new research students and staff are expected to undertake training in Research Integrity (and ethics where relevant), and it is your personal responsibility to undertake regular training to keep up to date with current good practice and statutory requirements, frameworks, standards, and obligations relevant to your field. Training should be reviewed within appraisal, training, or development conversations.

Staff must accept full responsibility for their own conduct and that of any staff, students and others under their direction or supervision. Team leaders must ensure that all researchers under their supervision/management have been suitably informed of and trained in their responsibilities under this Code and must be proactive in attempting to ensure that they undertake research in line with its provisions.

Data

Research data is data that you collect, observe, or create for purpose of producing original research.

[Personal data](#) is any data by which an individual could be identified. Particular care must be taken when handling 'special category personal data', i.e. data on racial or ethnic origin, political opinions, religious or philosophical beliefs, trade union membership, sex life or sexual orientation and the processing of genetic data, biometric data for the purpose of uniquely identifying a person, data concerning health or data concerning a natural person's sex life or sexual orientation.

The UoN supports [data sharing](#) as this allows independent validation and testing of data. It also ensures compliance with requirements of some publishers and funders.

All data management must adhere to relevant UoN policies and UK legislation:

- [UoN Research Data Management policy](#)
- [Handling Restricted \(personal sensitive\) Data policy](#)
- [UoN Information Security policies](#)
- [Data Protection](#)

The University provides support and guidance on creating data management plans

- UoN Research Data Management planning (see [Data Management Plan Toolbox](#))
- [Digital Research Pages](#)

Publications and Reports

This includes all reports on research from peer reviewed journal articles to internal interim reports or posts on social media. It is important that all research results (both novel findings and replication studies) are disseminated in an appropriate form, usually as papers in refereed journals. Academic papers can sometimes be misunderstood or misrepresented in the general media. Authors should consider how to avoid causing unnecessary distress or confusion to the general public.

The UoN supports Open Access to ensure maximum dissemination of results and the [University's Open Access policies](#) apply to all staff across all campuses.



You must acknowledge all contributors to the research (including students and technicians) in publications, by authorship or acknowledgement as appropriate to the research field. However you should not include as authors people who have not made a substantive contribution to the research.

- [‘Our Vision for Technical Talent’](#).

You must acknowledge all funding sources associated with the research.

Intellectual Property

IP includes, but is not limited to, research results in the form of data, inventions, notes, records, books, papers, designs, artwork, music, software, business methods, schemes for processing and assessing information and mathematical formulae. IP Rights are the legal rights that protect IP from inappropriate use or exploitation by others. If you think your work may have some commercial value, you should contact research.innovation@nottingham.ac.uk as soon as possible for further information.

- [UoN policy on Intellectual Property](#)
- Information can be found on Research and Innovation SharePoint pages [here](#).

Conflicts of Interest

If you have any pecuniary or non-pecuniary interests which may give rise to actual or perceived conflicts of interest in carrying out your work, then you should report them to your Head of School and the Registrar as soon as you become aware of them. The Registrar shall enter them on a register kept for this purpose.

- UoN Policy on [Conflicts of Interest, Gifts and Hospitality](#)

Insurance

The University holds insurance policies that provide indemnity for claims against both the University and the individual. You are responsible for checking and ensuring that all aspects of your research are covered by one or more insurance policy. Details can be found on the [Insurance Portfolio web page](#) or by contacting the University Insurance Officer.

International Research

If you plan to conduct research outside of the UK, you must be aware of the local regulations, practices and guidelines governing that research. All local permissions must be sought and in place before the research commences.

[Trusted Research Guidance for Academics](#)

- outlines the potential risks to UK research and innovation
- helps researchers, universities and industry partners to have confidence in international collaboration and make informed decisions around potential risks
- explains how to protect research and staff from potential theft, misuse and/or exploitation

You are legally obliged to find out if you need an export licence from the UK [Export Control Organisation](#) (ECO) for the transfer of goods, technology, software and/or knowledge to another country. For more information see SharePoint pages on [Export Controls Applying to Academic Research](#).

Access to Biological Material and Benefit Sharing

The UoN is committed to compliance with [Nagoya Protocol](#) which is an international agreement that implements the access and benefit sharing obligations in the Convention on Biological Diversity. It is intended to ensure that a genetic resource (or local knowledge of it) is not exploited without reference to the country or community in which it originated.

- Nagoya Protocol Implementation [Regulation \(EU\) No 511/2014](#)



Human Tissue

The collection and storage of human tissue is governed by the [Human Tissue Act 2004](#). The UoN is licensed by the Human Tissue Authority to oversee of the use of human tissues for teaching, research and training. If you want to store or use human tissue you must seek approval by the [HTMG designated individual](#), unless you are covered by current NHS ethical approval (HRA-REC) or the samples are processed and made acellular within 7 days of receipt. Email MS-HTA-enquiries@exmail.nottingham.ac.uk to check if your work needs to be brought under the licence.

The Prevent Duty and Security Sensitive Research

Section 26 of the Counter-Terrorism and Border Security Act 2019 places a duty on Higher Education institutions to have “due regard to the need to prevent people from being drawn into terrorism”. It is a criminal offence to obtain, possess or publish specified classes of information without a legitimate reason. Therefore, special measures are required for extremism-related research.

Research involving human participants

NHS Research Ethics Committees (NHS RECs) review and give ethical opinion to all research involving the NHS patients or their data and/or the use of investigational medicinal products or devices. The Research Governance Team reviews all applications for Sponsorship prior to the submission of approvals for such ethics and regulatory approvals. More information is available on the [Research Governance Team](#) pages.

All other studies involving human participants must undergo an ethical review process, through one of University’s Ethics Committees. The UoN’s [Code of Practice for Research Ethics Review Committees for Research Projects Involving Human Participants](#) outlines the minimum expectations for the operation of Research Ethics Review Committees in their ethical review processes.

Any research involving the use of Investigational Medicinal Products (IMPs) or medical devices will require the approval of the Medicines and Healthcare Products Regulatory Agency (MHRA). (Refer to Appendix A in the main Code for UNM procedures and processes). Standard Operating Procedures available on the RGS web page under Research Governance give instructions on how to do this.

Research Involving Animals

Where animals involved in the research the ethical review is carried out by the University’s Animal Welfare and Ethical Review Body (AWERB)

- [UoN Policy on the Use of Animals in Research](#)

Health and Safety

The health, safety and wellbeing of staff, students, research participants and visitors is fundamental to good research governance. You are expected to comply with all relevant health and safety regulations, policies and guidance.

- [UoN Safety pages provide policy, guidance and templates, and training](#)
- [Lone Worker Policy](#)

Equality, Diversity and Inclusion (EDI)

All research designs must take into consideration the effects on EDI. For instance exclusion and/or inclusion criteria should be clearly justified, particularly when considering *protected characteristics*.

Overview

1. Observance of the Code

The University of Nottingham requires all staff and students engaged in research to maintain the highest standards of ethics and integrity in the conduct of research. This **Code of Research Conduct and Research Ethics** (hereafter referred to as **the Code**) provides a framework for the governance of all research conducted under the auspices of the **University of Nottingham** (hereafter referred to as **the University**) and requires that all researchers adhere to the highest standards of ethical conduct, and to all applicable statutes and Government guidelines in carrying out their research.

The Code follows the principles set out in University Statutes (Section 35) and seeks to ensure that researchers have the academic freedom, within the law, to question and test received wisdom, and to put forward new ideas and opinions, controversial or unpopular, without placing themselves in jeopardy of losing their jobs or privileges.

The Code is designed to promote responsible research conduct in all stages of research and contains a framework for good research practice. The purpose of the Code is to assist all staff and students involved in research to meet legal and ethical requirements, and help prevent research misconduct, in order to facilitate high quality research.

The Code applies to all UK employees, students, visiting and Emeritus researchers, and honorary appointees, whether they are working on the University's premises or elsewhere. The Code applies to the University of Nottingham's International Campuses, University of Nottingham Ningbo China (UNNC) and University of Nottingham Malaysia (UNM) but it is understood that researchers at UNNC and UNM may be required to adhere to alternative or additional guidelines or conventions. [Appendix A](#) and [Appendix B](#) outline some of the adjustments which researchers at UNM and UNNC respectively may have to consider before commencing their research. In each section, reference is made, where applicable, to the relevant section in the appendices where protocols may differ. As a general rule, where the expected best practice differs between the UK, Malaysia and China it is expected that the research will adhere to whichever of the two sets of guidance presents the highest standards of research ethics or governance. This Code applies to collaborative research with other organisations and individuals outside of the institution who are undertaking or supervising research at or for the University.

The University's strategy set out its values (Inclusivity, Ambition, Openness, Fairness, and Respect) and expects all staff and students to follow the ethical standards set out in the Nolan Principles. Those are: selflessness, integrity, objectivity, accountability, openness, honesty and leadership. These principles underlie the University's Ethical Framework and are incorporated into this policy.

The Code applies to all research deliverables and outputs in whatever form, and to all research activity, as well as research conducted through consultancy, either conducted within or outside of the University of Nottingham and irrespective of how it is funded.

The document refers to "Schools" throughout to encompass Schools/Departments/Faculties/Centres, Institutes and Professional Service Departments, where this is appropriate.

2. The Context

The Code takes reference from and follows both the [Concordat to Support Research Integrity](#) and UK Research Integrity Office (UKRIO) [Code of Practice for Research](#) that encourage good conduct in research and help prevent research misconduct.

The UK Research Integrity Office (UKRIO) is an independent charity, offering advice, support and guidance on good research practice, and promoting integrity and high ethical standards in research, as well as robust and fair methods to address poor practice and misconduct to achieve research of the highest quality.

The Code links to and operates in conjunction with other University policies and procedures that form part of contracts of employment as well as the [Quality Manual](#). Some policies derive from Acts of Parliament, such as the Health and Safety at Work Act, Animals (Scientific Procedures) Act, Data Protection Act and the Medicines for Human Use (Clinical Trials) Regulations. Other policies derive from guidelines issued by government departments, such as the Department of Health's [UK Policy Framework for Health and Social Care Research](#). Refer to [Appendix A](#) for the UNM context and [Appendix B](#) for UNNC context.

Many funders of research have developed their own codes of conduct and/or detailed terms and conditions of award that must also be adhered to by grant holders, their host departments, and the host institution. Some terms and conditions may require confidentiality concerning the research. In some research areas there will be other considerations to be taken into account, such as profession-specific codes of conduct or practice and the need for specific qualifications or skills accreditation. Those undertaking research are required to observe new developments in their field and to meet any requirements for good research conduct as they arise. The Code also includes reference for [The Code of Practice on Handling Allegations of Research Misconduct](#).

The Code and its implementation are reviewed annually by the **University Research Integrity and Research Ethics Committee** (hereafter referred to as **URIEC**). The reviews take into account changes and recommendations from external research funders, Acts of Parliament and other legislation. All revisions are assessed and approved by URIEC and coordinated by Research and Innovation.

The University, its staff and students, and their research collaborators all share in responsibility for promoting and embedding good practice and high standards of research integrity within our institution's research culture.

3. Research Conduct

3.1 Foundations of Responsible Research Practice

Everyone involved in research in the University owes a duty of accountability and care to society, to their profession, to the University, to all participants in the research and to their funders as well as a duty of care to themselves. Staff must accept full responsibility for their own conduct of their research and the activities of all staff, students and others under their direction or supervision.

The core elements of '[The Concordat to Support Research Integrity](#)' (hereafter referred to as the **Concordat**) are the values from which trust and confidence in research stem, and from which the value and benefits of research flow. They apply to all aspects of research,

including the development of research aims and objectives, the preparation and submission of grant and project proposals, the acquisition and analysis of data, the publication and dissemination of findings and the provision of expert review on the proposals or publications of others.

They are:

- **honesty** in all aspects of research, including in the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.
- **rigour** in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.
- **transparency and open communication** in declaring potential competing interests; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes publishing or otherwise sharing negative or null results to recognise their value as part of the research process; and in presenting the work to other researchers and to the public.
- **care and respect** for all participants in research, and for the participants in, and users and beneficiaries of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the integrity of the research record.
- **accountability** of funders, employers and researchers to collectively create a research environment in which individuals and organisations are empowered and enabled to own the research process. Those engaged with research must also ensure that individuals and organisations are held to account when behaviour falls short of the standards set by the Concordat.

3.2 Responsibilities

Researchers must be able to exercise freedom in their academic choices and must also accept responsibility for the decisions that they make. Thus, the primary responsibility for ensuring that they act in accordance with these principles in all aspects of their research work, including peer review, lies with the individual researcher.

Researchers must commit to:

- understand the expected standards of rigour and integrity relevant to their research;
- maintain the highest standards of rigour and integrity in their work at all times;
- comply with ethical, legal and professional frameworks, obligations and standards as required by statutory and regulatory authorities, and by employers, funders and other relevant stakeholders;
- ensure that all their research is subject to active and appropriate consideration of ethical issues, including the wider impact of your research (see [Responsible research & innovation](#) for further information);
- keep their knowledge up to date on the frameworks, standards and obligations that apply to their work;

- collaborate to maintain a research environment that encourages research integrity;
- design, conduct and report research in ways that embed integrity and ethical practice throughout;
- act in good faith with regard to allegations of research misconduct, whether in making allegations or in being required to participate in an investigation, and take reasonable steps, working with employers as appropriate, to ensure that any recommendations made by formal research misconduct investigation panels are implemented;
- handle potential instances of research misconduct in an appropriate manner; this includes reporting misconduct to employers, funders and professional, statutory and regulatory bodies as circumstances require;
- declare and act accordingly to manage conflicts of interest.
- monitor and report any adverse events occurring in the course of their research according to the process in their School (e.g. Ethics Committee, Safety Office, Data Protection Officer etc.).

3.3 Training

An awareness and knowledge of research integrity contributes to the quality and excellence of research and helps to protect individual researchers, research participants and the research organisation. The training needs of researchers at all career stages should be considered to ensure that research project management skills reflect best practice in the sector. These should be discussed within the appraisal and development conversations process for staff or training plans for students.

URIEC requires all staff involved in research to undertake Research Integrity Training on regular bases to refresh their knowledge of developments in their field and the wider research integrity landscape. The University provides online Research Integrity Training, both a concise introduction and a comprehensive course which is designed to strengthen researchers' awareness of their own responsibilities and accountability and provides guidance on what to do should things go wrong.

It is a requirement that all new doctoral students undertake training in Research Integrity.

It is each researcher's personal responsibility to undertake the required training in current good practice and the statutory requirements relevant to their field.

4. Data

- 4.1. Research data:** is the data collected, observed, or created by further analysis to produce original research results. Research data may also include personal data and/or commercially sensitive data.

The management of all data should adhere to the regulations and the terms of relevant legislation and University policies such as the Data Protection Act (DPA) 2018, Research Data Management (RDM) ([UoN RDM Web](#)), and Secure Data Handling policies ([UoN Information Security](#)), and should adhere to any funder requirements. (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).

It is expected that all researchers have appropriately planned and documented the management of their research data throughout the project lifecycle and post closure and publication. The University provides support and guidance on creating data management plans (see [University's Research Data Management Policy](#) and [Digital Research Pages](#)).

Many research funders expect a Data Management Plan when applying for a grant. Some funders will require a regular review of the data management plan and make all necessary amendments while managing the grant.

- 4.1.1 Data which substantiates findings documented within associated research outputs, which has long-term value, or which is required to be retained by the funder, must be archived in accordance with the University's RDM policy and must be accompanied by appropriate metadata or documentation.
 - 4.1.2 Research data deposited for archive is retained and preserved for a period at least as long as that required by any funder, publisher or regulator of the research, or as set out in the University's Records Retention Schedule
 - 4.1.3 Confidentiality provisions relating to publications may apply in circumstances where the University or the researcher has made or given confidentiality undertakings to third parties or confidentiality is required to protect intellectual property rights. It is the obligation of the research leader to inform researchers as to whether confidentiality provisions apply and of researchers to enquire of their research leader whether there are any obligations with respect to these provisions
 - 4.1.4 Data must be stored in a managed environment, such as O365, to protect against data loss and corruption, unauthorised access and modification, and to comply with relevant ethical, legal, regulatory, contractual and intellectual property protection obligations
- 4.2. Personal data:** is any data by which an individual could be **identified**. Particular care has to be taken when handling '[special category data](#)' as defined under DPA which includes: racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation. (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).
- a) Only personal information pertinent to the research should be collected; valid grounds for data collection and processing must be identified
 - b) Special Category data under DPA must have a further lawful basis for processing
 - c) All staff and students using personal data in research have a duty of confidence to the individuals concerned; researchers must ensure that they have each study participant's explicit informed written consent to obtain, hold and use their personal information, unless there are ethically and legally justified reasons for doing otherwise.

- 4.3. Commercially-sensitive data:** must also be handled in accordance with the Secure Data Handling Policy (available at [UoN Information Security and Compliance](#)).

Researchers must familiarise themselves with the University's guidance which interprets the application of the DPA 2018 and any other relevant legislation that is pertinent to specific fields of research. Researchers must adhere to the principles of research data management, whereby research data should be made freely and openly available, in a timely and responsible manner with as few restrictions as possible; research papers should include a short statement describing how and on what terms any supporting research data may be accessed. If compelling legal or ethical reasons exist to protect access to the research data, these should be noted in a statement included in the published research paper.

4.4. Confidentiality

- a) An individual participant's personal information obtained as a result of research, is to be considered confidential and disclosure to third parties is prohibited. Exceptions may be made for some research, but participants must be advised of this in advance; this includes regulatory and monitoring purposes.
- b) Participant confidentiality should be ensured by using anonymisation techniques that are standard within the research field. When data cannot be fully anonymised, it should be pseudonymised as far as possible.

4.5. Open Access Publishing

The [University's Open Access policies](#) apply to all members of staff employed by the University at all campuses

- 4.5.1 All research papers (including journal articles, conference proceedings, book chapters and similar material), where copyright allows, should be made available in an open access form upon publication, unless this is explicitly forbidden by the publisher or other copyright holders.
- 4.5.2 All research papers (either in the form of the author's final accepted manuscript or published version/s) should be deposited in the Research Information System (RIS) upon acceptance by the publisher or as soon as possible thereafter, and, where copyright allows, made Green Open Access. (Refer to Appendix A for UNM guidance and Appendix B for UNNC guidance).
- 4.5.3 Researchers can take advantage of opportunities to publish their work in a Gold Open Access form offered by journal publishers and can seek to do this in one of three ways;
 - a. researchers can make use of Transformative Agreements between University of Nottingham and the publisher;
 - b. where open access publication fees apply researchers can make use of research grants to cover costs, or
 - c. Researchers with work funded by UKRI or certain health charities can apply for funding of Article Processing Charges against a block grant administered by the University.
[\[https://www.nottingham.ac.uk/library/research/open-access/requesting-oa-funding/funding.aspx\]](https://www.nottingham.ac.uk/library/research/open-access/requesting-oa-funding/funding.aspx).

4.6. Data Sharing

[Sharing data](#) supports the integrity of research by allowing data to be independently validated and tested. It also ensures compliance with mandates set by some publishers and funders. Publishing data should align with the [FAIR](#) (Findable, Accessible, Interoperable and Re-useable) principles which support discoverability through good data management.

- 4.6.1 Data should not be shared and does not require a publicly available metadata record if the research project and metadata describing it are themselves confidential, as stipulated by the funder or as recommended by Research Ethics Committee (hereafter referred to as a **REC**) or the data asset owner.
- 4.6.2 Personal data should only be shared in line with the individual's informed consent and using appropriate safeguards. Otherwise, the data should be anonymised or pseudonymised. Guidance on consent for data sharing can be found at the [UK Data Service](#).
- 4.6.3 Research data deposited for archive should be made discoverable, via a publicly available metadata record, no later than the publication date of associated research outputs, subject to legal, ethical, contractual or commercial constraints.
- 4.6.4 Research data deposited for archive should be made available for sharing with as few restrictions as possible whilst remaining in line with funder and regulatory requirements. This should be achieved through the assignment of a clear and accessible data usage licence.

5. Publications and Authorship

All forms of dissemination, whether through publications, websites, e-bulletins, press releases, media briefings, or events should be undertaken with the core principles of openness, transparency and accountability.

Publications include reports and technical reports related to a programme of research (including internally and externally funded research), even where these have a limited circulation and have been prepared to report on progress of the research.

Researchers are encouraged to disseminate their research and research findings in an appropriate form, usually as peer-reviewed journal articles. Publication and wider dissemination of research and research findings must be carried out responsibly and with an awareness of the consequences of dissemination in the wider media.

- 5.1. Decisions on publication and authorship should be agreed jointly and communicated to all members of the research team, and ideally this should be discussed before the publication is written.
- 5.2. Everyone who fulfils the criteria for authorship should be included as author of submitted work. 'Team science' is becoming increasingly common with research teams spanning different specialties and locations. Therefore, the contributions of all members of the research team must be properly recognised. This could include students, data scientists, data engineers, archivists, informaticians, statisticians, software developers, audio-visual technologists, [technical](#)

[professional staff](#) and individuals staffing core facilities, across all disciplines. The UoN was a founding signatory of the [Technical Commitment](#).

- 5.3. Authorship should be restricted to those who have made a significant intellectual or practical contribution to the work. Authorship should not be allocated to “guest” or “gift” authors.
- 5.4. Contributions of those who do not meet the criteria for authorship should be listed in the acknowledgements section (with their permission).
- 5.5. Data sourced from third parties, facilitation to access data, use of equipment or samples must be acknowledged.
- 5.6. Anyone listed as an author of any work should be prepared to take public responsibility for that work and ensure its accuracy, and be able to identify their contribution to it.
- 5.7. All funders and sponsors of research should be clearly acknowledged, and any competing interests listed. Researchers should be aware that their funder may want to be notified in advance of paper submission, publication or other dissemination.
- 5.8. Individuals who are or have been the participant of the research should not be identified or identifiable in any publication, unless they have explicitly consented to have their identity revealed.
- 5.9. Submitting research reports to more than one potential publisher at any given time (i.e. duplicate submission) or publishing findings in more than one publication without disclosure and appropriate acknowledgement of any previous publications (i.e. duplicate publication) is unacceptable.
- 5.10. A publication which is relates to other publications derived from the same research must contain appropriate reference to the other publications.

(Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).

6. Intellectual Property

The University has specific policies arising from Intellectual Policy and these must be adhered to.

6.1. Intellectual Property (IP) and Intellectual Property Rights (IPR)

IP is defined as: "The products of creative effort". It includes, but is not limited to, the results of research in the form of data, inventions, notes, records, books, papers, designs, artwork, music, software, business methods, schemes for processing and assessing information and mathematical formulae. IP Rights are the legal rights that protect IP from inappropriate use or exploitation by others. The forms of IPR are limited and in the UK consist of the following:

- Patents
- Copyright
- Database rights (form of copyright)
- Registered and unregistered design rights
- Plant breeders' rights

- Registered and unregistered trademarks

6.2. Intellectual Property Ownership and the University

IP generated by University employees belongs to the University if it was made in the course of normal duties or during circumstances where an invention might reasonably be expected to take place. Unfettered IP (not owned by a third party) generated by students belongs to the student. If the inventorship is shared with a member of staff and the University elects to protect the IP, the University will request the student to assign their rights to the University. If you believe that you have generated IP during the course of your research, you should contact the IP Office who will send an IP assessor to take details of the IP or 'disclosure'. The University will assess the IP and determine whether or not to protect and commercialise the IP. If the University elects not to proceed it will assign its rights to the inventor(s). Full details of the University's policies on and procedures for IP and IPR can be found on Research and Innovation Pages [here](#).

Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance on intellectual property.

7. Supervision and Leadership

Schools must adopt guidelines for the supervision of research undertaken by staff and students in accordance with requirements prescribed from time to time by the Senate and as specified in the [Quality Manual](#) for Staff and Students. The workload of all staff carrying out research shall be considered and moderated by research team leaders, Chief/Principal Investigators and Directors of Research or Heads of Schools as appropriate.

The University, research staff, particularly team leaders, supervisors and Chief/Principal Investigators, must take responsibility for ensuring that all researchers under their supervision/management have been suitably informed and trained of their responsibilities under this Code and that they undertake research in line with its provisions. They must take responsibility for:

- a) The ethical basis and design of their research projects. Researchers must ensure that research projects are ethically sound and have received the Favourable Ethical Opinion (FEO) of the relevant REC and all relevant statutory regulatory authorities have approved before they commence;
- b) The safety of all those involved in the research process, ensuring that the research is carried out in accordance with [health and safety policies](#) and legislative requirements;
- c) Ensuring that research is conducted in a suitable working environment with appropriate equipment and facilities;
- d) The probity of the financial management of research projects, and the timely delivery of any scheduled tangible outcomes;
- e) Management of research data in accordance with funders requirement and in compliance with the [Data Protection Act 2018](#) and any other legal provisions, conditions and guidelines that may apply to the handling of personal information (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance);
- f) Undertaking sufficient professional development appropriate to the research;
- g) Ensuring that all records of research progress, including authorised laboratory books, are maintained to the recommended or required standards, and ensuring that the falsification of results does not occur.

- h) Ensuring confidentiality in order to achieve protection of intellectual property rights where appropriate;
- i) Ensuring that research findings are suitably disseminated and as agreed with the funder;
- j) Ensuring voluntary participation and informed consent of research participants, free from any coercion. It is recognised that even retrospectively this may not be possible for some types of covert research.
- k) Avoiding harm to participants and minimising the potential for any adverse effects that the research may have on people, animals and the natural environment and property.

8. Funder Requirements

Guidelines for the project management, costing and pricing and authorisation of research proposals with external funders can be found on the University's Research and Innovation [pages](#).

All research grant applications and commercial research contracts whose Principal or Chief Investigator is employed by the University must be approved by the relevant authoriser and the Head of School or equivalent unit (see [Application and approvals pages](#)) (Refer to [Appendix A](#) for UNM guidance). Researchers have a responsibility to read the terms and conditions of funders and contractors before signing grant applications to ensure that they understand the implications of those terms and that they agree to and accept them as a basis for that research.

Where research is funded by more than one funding body or contractor, researchers have a responsibility to read the terms and conditions of the different funding bodies to ensure they understand and agree to the terms and to ensure there is no conflict between the terms and conditions of the different funding bodies.

9. Conflicts of Interest

Conflicts of interest may occur where researchers have an affiliation or financial involvement (including direct financial interest, provision of benefits and provision of material or facilities) with more than one organisation sponsoring or providing financial support for research.

The University has a [Policy on External Work](#) undertaken by those on Research and Teaching contracts (R&T 4a-7), Clinical Academics, Fertility Nursing Services, Administrative, Professional and Managerial staff (APM4-7), and Technical Services (TS 4&5). This policy states that external work, whether or not remunerated, has to be regulated in order to ensure that either it does not create a conflict of interest or, if necessary, it has received formal sanction from the University. The policy sets out cases where permission to carry out external work is automatic, procedures by which permission may be sought in other cases, and the consideration that will be taken into account when it is decided whether permission shall be granted.

The University policy on [Conflicts of Interest, Gifts and Hospitality](#) states that if members of staff have any third party pecuniary or non-pecuniary interests which may give rise to conflicts of interest in carrying out their University duties, they should report them to their Head of School and to the Registrar. The Registrar shall enter them on a register kept for this purpose.

Researchers must identify, openly declare and address all real or potential conflicts of interest at all stages of their research project, as soon as they become aware of them, in order to avoid poor practice in research or potential misconduct.

Where there is a potential Conflict of Interest in research that falls outside the areas covered by the above policies, this must be discussed with the relevant Head of School, Associate Faculty Pro-Vice Chancellor (AFPVC) or FPVC at the earliest opportunity. The FPVC and/or AFPVC may refer or confer any potential conflicts of interest to/with the Director of Research and Innovation and/or the Pro-Vice Chancellor Research and Knowledge Exchange. Refer to [Appendix A](#) for how this applies to UNM and [Appendix B](#) for how this applies at UNNC.

When addressing a conflict of interest, it must be decided whether it is of a type and severity that poses a risk of compromising the validity or integrity of the research, in which case researchers should not proceed with the research, or whether it can be adequately addressed through declarations and/or special safeguards relating to the conduct and reporting of the research.

10. Adverse Events

Researchers are responsible for monitoring and reporting any adverse events occurring in the course of the research and each School must have systems in place to ensure that all such adverse events are recorded and, if appropriate, investigated.

Adverse events can be defined as untoward events in the research process that could potentially compromise the safety of researchers, research participants, or the integrity of the research, breach the regulations or the conditions of the favourable ethical opinion or the approval for the study.

For clinical/medical research, where Health Research Authority approval has been sought and received a favourable ethical opinion from NHS Research Ethics Committee, standard Operating Procedures available on the [Research Governance Pages](#) give instructions on how to meet these reporting requirements. Refer to [Appendix A](#) for variations in application on the UNM campus.

11. Insurance

The University holds insurance policies that provide indemnity for claims against both the University and the individual for:

- 11.1.** Property and business interruption;
- 11.2.** Employers liability: this covers for claims made for death, injury or disease to any person arising out of and in the course of their employment;
- 11.3.** Public liability: this provides indemnity in respect of claims made for death, injury or disease to persons other than employees or loss or damage to third party property arising out of and during the course of the business;
- 11.4.** Professional indemnity: this provides indemnity in respect of legal liability to third parties for breach of professional duty due to negligent act, error or omission in connection with your business; and

- 11.5. Clinical trials: this provides indemnity against legal liability for damages in respect of accidental injury of any research participant arising out of the business of conducting clinical trials

Each separate policy carries specific inclusions and exclusions. The Employer's Product and Public Liability policy extends world-wide. All the other policies are limited to Great Britain (England, Scotland, and Wales), Northern Ireland, the Channel Islands and the Isle of Man.

Researchers are responsible for checking and ensuring that all aspects of their research are covered by one or more insurance policy.

Details can be found on the Insurance Portfolio web page or by contacting the University Insurance Officer.

Refer to [Appendix A](#) for details of the UNM policy.

12. Additional Requirements

Any special requirements that are imposed by law or by the University for particular categories of research are included in this Code. Project managers have a responsibility to inform staff about any implications and ensure that they understand and accept the requirements.

12.1. International Research Collaborations

When proposing to conduct research overseas, researchers from the University of Nottingham UK campus have a responsibility to inform themselves and be aware of the regulations, local practices and guidelines governing that research within individual countries. (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).

All local permissions where the research is to be conducted must be sought and in place before the research commences.

Many research collaborations of two or more institutions may be subject to more than one ethical review procedures. The lead researcher/s should establish the requirements of each institution involved and whether a favourable ethical opinion by one institution is sufficient for the others involved. This also applies where there are sub-projects/studies within a programme of research, whereby each sub-study may require separate ethical review. It is essential for researchers to establish both local ethical and legal requirements in addition to the University's requirements.

The University Insurance Officer must be informed of the proposed research activity so that any insurance issues can be clarified and resolved before the research starts. (Refer to [Appendix A](#) for variations to this guidance for UNM research). Special consideration should be given to the transfer of human or animal tissues and data sharing between countries. Laws and practices of all countries involved in the research must be adhered to simultaneously.

Any medical research that is proposed to be conducted overseas must firstly be discussed with the Head of Research Governance (Refer to [Appendix A](#) for UNM guidance). The University does not carry insurance for medical research conducted overseas and there are special arrangements for such research that must be in place before it can go ahead. The ethical opinion sought from the National Research Ethics Service (NRES) for UK based medical research is not applicable overseas. All local regulations and customary practices must be adhered to in each country proposed to take part in the research.

Similarly, UK based researchers are responsible for ensuring that, in any international research collaborations, the conduct of the research being undertaken in the UK abides to applicable UK law. Any conflict with other collaborating countries' laws and practices must be resolved before the research starts (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).

Researchers should refer to country-specific guidelines for the location where research is being carried out where possible. [The International Compilation of Human Research Standards](#) is a [listing by the US Department of Health and Human Services](#) of over 1,000 laws, regulations, and guidelines (including ethics committees) on human participants' protection in over 100 countries and from several international organisations. Details of country-specific requirements and how these are met should be included in the ethics application and study documentation.

Researchers should be aware of and apply the UK Government's National Cyber Security Centre guidance on "[Trusted Research](#)" which sets out how to identify risks and protect research data in the UK's research and innovation sector. It was developed with input from several universities (including the University of Nottingham) as well as a wider range of researchers (including researchers at the University of Nottingham) with aims to support the integrity of the system of international research collaboration, which is vital to the continued success of the UK's research and innovation sector. It is particularly relevant to researchers in STEM subjects, dual-use technologies, emerging technologies and commercially sensitive research areas.

Trusted Research:

- Allows the identification and management of potential risks to your Research/ Knowledge Exchange activities
- Helps researchers, UK universities and industry partners to have confidence in international collaboration and make informed decisions around those potential risks
- Explains how to protect research and staff from potential theft, misuse or exploitation

See SharePoint pages for [Trusted Research Toolkit](#) and available support.

12.2. Export Controls

'Export' means the physical removal of goods or the transfer (by any means) of technology or software and/or knowledge from the UK to a destination outside the UK, incl. via email, fax, video-conferences and shared data environments. Technology means 'specific information' necessary for the 'development', 'production' or 'use' of goods or software that is not in the public domain.

Export Control involves regulation of cross border transfers of certain types of goods, technology and information. Export controls apply to controlled items such as military equipment, so called "dual-use goods" and to the technology related to them.

As a researcher you must understand how to comply with any export licences that apply to the projects you are working on. Failure to comply with this law can result in fines, legal costs or prison sentences of up to 10 years. The Export Control Joint Unit can, and will, hold individuals accountable.

As a Principal Investigator you are responsible for:

- understanding whether export control applies to any aspect of your project and whether you require a licence.
- ensuring that you have necessary licences and are complying with export controls.
- checking that all members of your research team understand and are complying with the conditions of export licences throughout your project.
- keeping adequate records of what you have done, and where materials and information are located.
- helping to prevent suspected illicit transfers.

Researchers need to check whether their work, technology, equipment, materials, software or know-how is on any of the [UK Strategic Control Lists](#).

Researchers may find it helpful to think about intellectual property, information security and export controls as three points of a triangle, and to consider them together. The Department for Business, Innovation & Skills (BIS) and Foreign and Commonwealth Office (FCO) [Higher Education Guide and Toolkit on Export Controls](#) (PDF) provides:

- A broad summary of UK export controls in relation to academia;
- An explanation of where the various exemptions apply;
- A discussion of what this means in practice for academics;
- A decision tree; and
- Illustrative case studies.

The University is registered on [SPIRE](#) (the ECO's online export licensing system) so that researchers can submit licence applications and queries can be submitted.

For further information and guidance see SharePoint pages on [Export Controls Applying to Academic Research](#).

12.3. Access to Biological Material and Benefit Sharing

The University of Nottingham is committed to compliance with the [Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation to the Convention on Biological Diversity](#) and the EU's Nagoya Protocol Implementation Regulation ([Regulation \(EU\) No 511/2014](#)).

The [Nagoya Protocol](#) is an international agreement that implements the access and benefit sharing (ABS) obligations of the Convention on Biological Diversity. It is intended to ensure that a genetic resource (or local knowledge about it) is not exploited without reference to the country or community in which it originated.

Researchers who source or use resources in scope of the Protocol are required to ensure that genetic resources, and traditional knowledge associated with those resources, have been accessed in accordance with applicable access and benefit sharing laws implemented by the source country. For further details please see [Biodiversity SharePoint pages](#).

Refer to [Appendix A](#) for UNM guidance on the Nagoya Protocol.

12.4. Human Tissue in Research

In the UK, the collection and storage of human tissue is governed by the [Human Tissue Act 2004](#). The University of Nottingham is licensed by the Human Tissue Authority for oversight of the use of human tissues for teaching, research and anatomical training.

Individuals wanting to store or use human tissue must seek approval by the HTMG designated individual, unless they are covered by current NHS ethical approval (HRA-REC) or are processed and made acellular within 7 days of receipt. Please email MS-HTA-enquiries@exmail.nottingham.ac.uk to check if your work or holdings needs to be brought under the licence.

12.5. Criminal Offences concerning obtaining, possessing or publishing information

- a) In certain circumstances it is a criminal offence to obtain, possess or publish specified classes of information unless a defence is established (e.g. that this is done for a legitimate reason as for proper teaching or research purposes). Other offences apply to the publication in particular circumstances of threatening, abusive or insulting material.
- b) Guidance can be found in the UUK document Freedom of Speech on Campus: rights and responsibilities in [UK Universities \(2011\)](#)
- c) If any member of staff wishes to seek advice on the application of this or similar legislation, they should contact the [Registrar's office](#) (registrars@nottingham.ac.uk) in the first instance.
- d) Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance.

12.6. The Prevent Duty and Security Sensitive Research Data

Section 26 of the Counter-Terrorism and Border Security Act 2019 (the Act) places a duty on certain bodies (specified authorities) in the exercise of their functions, to have “due regard to the need to prevent people from being drawn into terrorism” and obtaining or viewing material over the internet. Higher Education organisations are a specified authority and therefore have an obligation under the [Prevent Duty](#). In particular, the Prevent Duty Guidance states that “To enable the university to identify and address issues where online materials are accessed for non-research purposes, we would expect to see clear policies and procedures for students and staff working on sensitive or extremism-related research”. The University’s existing ethical review procedures and checklists are designed to identify and effectively review this type of research. Further guidance can be found in the Policy for Ethical Review and Frequently Asked Questions.

13. Health and Safety

The health, safety and wellbeing of staff, students, research participants and visitors is vitally important. Health and safety have a vital role in supporting and enabling world leading teaching and research.

In order to achieve this, the University ensures an effective management of risks by setting, implementing and continually improving health and safety management systems. University policies establish standards and expectations for health and safety across the organisation and set the minimum standards expected. In some instances, it may be appropriate to provide a set of Local Rules for a particular laboratory or suite of laboratories or individual research projects where a less common hazard is encountered, or highly specialised work carried out. The Safety Office should be consulted to examine drafts and advise on these documents (bb-safety-office@exmail.nottingham.ac.uk).

The Universities and Colleges Employers Association and the Universities Safety and Health Association have worked with the Institution of Occupational Safety and Health, the

Medical Research Council and others to produce useful guidance that covers a wide range of research fields.

The guide ([Responsible research: managing health and safety in research](#)) aims to help anyone who needs to ensure good health and safety performance in a research environment. It provides heads of department, principal investigators and researchers with:

- examples of responsibilities and management approaches
- advice on safety culture and risk assessment
- case studies showing key issues that need to be considered.

Researchers are expected to comply with all health and safety regulations, policies and guidance relevant to their work. It is important to also recognise that some of these policies are derived from legislation and conform to legal and standards requirements. The University's [Health and Safety pages](#) provide policy, guidance and templates, in addition to training for all staff and students to help meet their needs.

13.1. Lone Working

Where research involves lone working or contact with research participants outside of the University premises the [University Policy and Guidance on Lone Working](#) should be adhered to. It is expected that all research activities, including lone working, are risk assessed prior to commencement. Particular consideration should be given to lone working where there are vulnerable populations of research participants involved (such as children or adults with a mental incapacity).

14. Equality, Diversity and Inclusion (EDI)

The University's goal for EDI is to ensure students and staff feel comfortable, safe, included and supported to be their very best in all that they do; that the University is the best it can be, with a high performing and diverse staff and student community; and that all students and staff visibly contribute to the values of the University and its wider impact.

The University will solve problems and improve lives through education, research and knowledge exchange of the highest quality and create an inclusive environment in which students and staff are treated solely on the basis of their merits, regardless of any *protected characteristics*. The Equality Act 2010 defines these as: age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex, and sexual orientation. Our duty under the Equality Act 2010 to eliminate unlawful discrimination, harassment and victimisation, advance equality of opportunity and foster good relations in everything it does, including research.

UKRI expect those in receipt of Research Council funding to:

- promote and lead cultural change in relation to equalities and diversity
- engage staff at all levels with improving the promotion of equality and diversity
- ensure all members of the research workforce are trained and supported to address disincentives and indirect obstacles to recruitment, retention and progression in research careers
- provide evidence of ways in which equality and diversity issues are managed at both an institutional and department level

It is important for research designs to take into consideration the implications on EDI aspects. Research participants' exclusions and/or exclusion criteria should be ethically assessed and clearly justified in particular when touching on *protected characteristics*.

15. Research Misconduct

The University of Nottingham is committed to maintaining the highest standards of integrity, rigor and excellence in all aspects of our research and for all research to be conducted according to the appropriate ethical, legal and professional frameworks and standards.

Research misconduct is a serious matter, and those responsible for staff and postgraduate research students conducting research have a duty to ensure that those new to research or to the University receive appropriate training in the ethical, legal and other conventions concerning the conduct of their research.

The University seeks to provide a research environment that fosters and supports honesty in research and discourages unacceptable behaviour by dealing seriously and sensitively with all allegations of research misconduct.

In most instances, concerns about the conduct of research are likely to be resolved informally without the need for a formal process being initiated. Concerns about the conduct of research can be raised by a participant in the research, a student or member of staff, or a member of the public. Research and Innovation will act in an advisory and support capacity to assist the process in cases of potential Research Misconduct.

In line with the [Concordat to Support Research Integrity](#), “*Research misconduct is characterised as behaviours or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. It can cause harm to people and the environment, wastes resources, undermines the research record and damages the credibility of research*”. This definition aligns with the principles of “*The Singapore Statement on Research Integrity*”.

The University recognises that academic freedom is fundamental to the production of excellent research. Therefore, the responsibility for ensuring that no misconduct occurs rests primarily with the individual researcher.

15.1. Research misconduct can take many forms, including:

- 15.1.1. **fabrication**: making up results, other outputs (for example, artefacts) or aspects of research, including documentation and participant consent, and presenting and/or recording them as if they were real
- 15.1.2. **falsification**: inappropriately manipulating and/or selecting research processes, materials, equipment, data, imagery and/or consents
- 15.1.3. **plagiarism**: using other people’s ideas, intellectual property or work (written or otherwise) without acknowledgement or permission
- 15.1.4. **failure to meet**: legal, ethical and professional obligations, for example:
 - a) not observing legal, ethical and other requirements for human research participants, animal subjects, or human organs or tissue used in research, or for the protection of the environment
 - b) breach of duty of care for humans or animals involved in research whether deliberately, recklessly or by gross negligence, including failure to obtain appropriate informed consent where relevant.
 - c) misuse of personal data, including inappropriate disclosures of the identity of research participants and other breaches of confidentiality

- d) improper conduct in peer review of research proposals, results or manuscripts submitted for publication. This includes failure to disclose conflicts of interest; inadequate disclosure of clearly limited competence; misappropriation of the content of material; and breach of confidentiality or abuse of material provided in confidence for the purposes of peer review

15.1.5. misrepresentation of:

- a) data, including suppression of relevant results/data or knowingly, recklessly or by gross negligence presenting a flawed interpretation of data
- b) involvement, including inappropriate claims to authorship or attribution of work and denial of authorship/attribution to persons who have made an appropriate contribution
- c) interests, including failure to declare competing interests of researchers or funders of a study
- d) qualifications, experience and/or credentials
- e) publication history, through undisclosed duplication of publication, including undisclosed duplicate submission of manuscripts for publication

15.1.6. Improper dealing with allegations of misconduct: failing to address possible infringements, such as attempts to cover up misconduct and reprisals against the complainant, or failing to adhere appropriately to agreed procedures in the investigation of alleged research misconduct accepted as a condition of funding.

15.2. Honest errors and differences of opinion in, for example, research methodology or interpretations do not constitute research misconduct. Misconduct does not include honest errors and differences of opinion related to the design, execution, interpretation or judgement in evaluating research methods or result.

15.3. Allegations of misconduct in research will be judged by the standards prevailing at the time that the behaviour under investigation occurred.

15.4. Allegations of research misconduct will be referred to the employing or degree awarding institution at the time the alleged misconduct took place.

15.5. For further information please see the [University's Code of Practice on Handling Allegations of Research Misconduct](#). It also applies to UNM and UNNC (Refer to [Appendix A](#) for UNM guidance and [Appendix B](#) for UNNC guidance).

16. Research Ethics

The University of Nottingham's core key principles for ethical research will apply to all its research.

1. Maximising Benefit
2. Minimising Harm
3. Respecting Autonomy
4. Fairness and Accountability
5. Integrity and Transparency

New situations constantly emerge in the research arena which may require creative approaches to the ethical challenges they pose.

Researchers are responsible for ensuring that their research is conducted to the highest ethical standards. Researchers must ensure that they are fully aware of, and comply with,

the University's expectations for the ethical conduct of research and the ethical requirements of research funders, professional bodies and/or the expectations of their research discipline.

All the ethical implications of a research project must be considered, including the impact on:

- all those involved in the research;
- those who may be affected by it;
- the welfare of animals;
- cultural sensitivities;
- protected species and sites;
- and the environment.

Researchers must consider their own safety and wellbeing and comply with all relevant University policies and guidance, including the Lone Worker Policy.

Consideration of ethical issues has long been a feature of medical research and most notably has its origins in the *Nuremberg Code 1947*, following the trials of the Nazi war criminals. It is one of the most influential documents in the history of the ethics of medical research and the first of its kind to ensure the rights of participants. The Nuremberg Code sets out principles such as informed consent and absence of coercion; properly formulated scientific experimentation; and beneficence towards research participants.

[The Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects](#) first issued in 1964, is the policy-statement of the World Medical Association. Although this text was written primarily for medical practice, many of the principles have general application; for example, regard for human dignity; care for human and animal welfare, consideration of risk, and informed consent of human participants in research projects.

Many statutory, professional and regulatory and other bodies, for example Research Councils, have adopted either Codes of Practice or Guidelines. Two examples are the UK Economic & Social Research Council's *Research Ethics Framework* and *Respect Code of Practice for Socio-Economic Research* which is intended to form the basis of a professional voluntary code covering the conduct of social-economic research in Europe.

16.1. Research Ethics Review Committees

The University of Nottingham operates a devolved structure for ethical review, reflecting the diverse nature of research across the University. The University of Nottingham has a dedicated [Code of Practice for Research Ethics Review Committees for Research Projects Involving Human Participants](#) which outlines the minimum expectations for the operation of Research Ethics Review Committees in their ethical review processes and specific guidance on the operation of School, Department or Faculty Research Ethics Review and associated processes, including review criteria. Whilst this Code outlines the guiding principles for conducting research, the Code of Practice for Research Ethics Review Committees provides guidance on the processes and procedures to follow in research ethical review.

The National Health Service (NHS) was the first public body in the UK to give effect to these principles. The operation of RECs in the NHS is coordinated through the Health Research Authority's (HRA) Research Ethics Service (RES). HRA RES review and give ethical opinion to all research involving the NHS patients or their data and/or the use of investigational medicinal products or devices. **The University of Nottingham recognises and accepts the HRA RES ethical opinion.** The University of Nottingham Research Governance Team reviews all applications for Sponsorship prior to the submission of

approvals for ethics and regulatory approvals. Standard Operating Procedures available on the University's [Research Governance pages](#) which set out instructions on how this is done.

16.2. University Research Ethics Committees

URIEC is responsible for all Research Ethics Committees within the University of Nottingham. URIEC has REC members representing each of the five faculties and China and Malaysia campuses.

The purpose of ethical review within the University covers three core functions:

- i) The University is committed to following good ethical practice, as a principle in itself and as a means by which the public can have confidence in the work of staff and students of the University.
- ii) The provisions for ethical review and favourable opinion assist researchers in the identification of ethical issues and how to address them in the structuring of research protocols and the conduct of their research. The resultant development of good practice is expected to cascade down to students and inform their own emerging practice at both undergraduate and postgraduate level.
- iii) The ethical review process acts as a safeguard for researchers, supervisors and students who can be confident of the ethical propriety of their project once it has been approved.

16.3. Ethical review and processes

Every research project must go through some form of an ethical assessment. Ethical review (and favourable ethical opinion) is required where the research involves the participation of human participants (participants, see Section 17 for definition), their data and/or their tissue (see criteria for ethical review [Code of Practice for Research Ethics Review Committees](#)).

Where the use of animals is involved, this is subject to regulation and the ethical review is carried out by the University's Animal Welfare and Ethical Review Body (AWERB) – see section 16.3.7– in line with the legislation.

Researchers are advised that if in doubt about the need for an ethical review of their research to speak to their [School Ethics Officer or committee](#). Responsibility for ensuring proper ethical review lays with the Chief/Principal Investigator or the Student Supervisor.

In addition to complying with the University's internal policies, each School must ensure that systems are employed to review the ethical implications of research undertaken by its academic and research staff and students before any research commences.

Heads of Schools who are able to support research with School funds must ensure that Research staff are especially vigilant regarding the potential need to seek the opinion of one or more ethics committees. If there is any doubt about the need for ethical review in relation to their proposed research, staff should seek advice from their School Research Ethics Officer.

16.3.1. Research involving human participants

For the purposes of this Code, research involving human participants is divided into non-medical research and medical or clinical research.

16.3.2. Non-medical research

Non-medical research involving human participants is reviewed internally via the researcher's Faculty or School's REC or through an agreed designated reviewing process through another School's committee.

16.3.3. Medical or clinical research

Generally, pre-clinical, physiological, medical, health and social care related research, which does NOT involve NHS patients or prisoners, is reviewed by the Faculty of Medicine and Health Sciences REC.

Medical or clinical research involving NHS resources, staff, patients and biological materials or data derived from them and ALL clinical research involving the use of Investigational Medicinal Products (IMPs) or medical devices on human participants must be approved by the HRA and/or gain a UK registered ethics committee's favourable ethical opinion (as applicable) (see www.hra.nhs.uk). Standard Operating Procedures are available on the [Research Governance SharePoint](#) pages (Refer to [Appendix A](#) for UNM procedures and processes).

a. Medical or clinical research involving NHS resources, staff, patients and biological materials or data derived from them and ALL clinical research involving the use of IMPs or medical devices on human participants requires the nomination of a Research Sponsor. The University of Nottingham acts as the Research Sponsor for all of its medical/clinical research where appropriate. The Research Governance Team reviews all applications for Sponsorship prior to the submission of approvals for ethics and regulatory approvals. For more information and guidance please see the University's [Research Governance Team](#) SharePoint pages.

b. Any research involving the use of Investigational Medicinal Products (IMPs) or medical devices will also require the approval of the Medicines and Healthcare products Regulatory Agency (MHRA). (Refer to [Appendix A](#) for UNM procedures and processes). The Chief Investigator is responsible for obtaining approval where it is appropriate. For more information and guidance please see the University's [Research Governance Team](#) SharePoint pages..

16.3.4. Research involving participation by children or vulnerable adults

Research that involves participation by children (under 16 years old) or vulnerable adults such as those with a mental incapacity or prisoners should undergo an ethical review by a suitable ethics committee detailed in section 15 depending on the nature of the research. See also 7.2 (refer to [Appendix A](#), Section 7 for UNM guidance). Researchers involving adults lacking mental capacity must ensure that they are familiar with the requirements of the legislations, particularly the UK Mental Capacity Act before designing their research (See HRA guidance on [Mental Health Capacity Act](#)). Advice can be sought from the Head of Research Governance.

16.3.5. Disclosure and Barring Service

The Disclosure and Barring Service (DBS) falls under the Protection of Freedoms Act 2012 and merges the functions previously carried out by the Criminal Records Bureau (CRB) and Independent Safeguarding Authority (ISA).

Where the research involves participation of children or vulnerable adults the participating organisation via whom the researcher hopes to recruit the study participants, may request a DBS check of the researchers, and researchers must be prepared to undertake this. Refer to Appendix A for how this applies to the UNM campus.

The DBS is an Executive Agency of the Home Office and its aim is to help organisations in the public, private and voluntary sectors by identifying candidates who may be unsuitable to work with children or other vulnerable members of society.

16.3.6. Occluded or Covert Research

Occluded research is where full information cannot be given to the research participant because this would introduce bias (such as the participant's knowledge of use of a placebo); be meaningless (such as in crowd observation); or invalidate the research (such as in certain psychological experiments).

Research may be undertaken in a covert way where the full written informed consent of the participant cannot be obtained because this may pose a risk (such as criminal disclosure) to the participant; or where the research necessarily involves concealment of the real objectives of the research without knowledge of this by the research participants. Thus the people being studied are not fully informed about the research. There are different types of covert research, and these can include concealment, misrepresentation, and camouflage. All of these raise a number of ethical issues.

The appropriate REC to conduct the ethical assessment depends on the nature of the research and whether the research is of a medical basis or not.

- a. The withholding of information from participants should only occur when the researcher is clear that the aims and objectives of the research cannot be achieved by any other means and that the welfare of the participants is assured.
- b. Covert methods necessarily violate the principles of informed consent and may invade the privacy of those being studied. Participant observation in non-public spaces or experimental manipulation of research participants without their knowledge should be resorted to only where it is impossible to use other methods to obtain essential data. In such studies it is important to safeguard the anonymity of research participants.
- c. Where it is possible and practicable, and where it is judged that the consequences of doing so will not be harmful (e.g. cause distress) to participants and will not potentially jeopardise the research, disclosure and debriefing should follow participation as soon as possible. Here the participant should be offered the option of withholding their data in accordance with the principle of participation by informed consent.

16.3.7. Research and Teaching involving the use of animals

The Animals (Scientific Procedures) Act 1986 (ASPA) stipulates that a section 2C establishment licence must include a condition requiring the holder to establish and maintain an Animal Welfare and Ethical Review Body (AWERB). See [page 88 of the Guidance on the Operation of ASPA](#).

The University of Nottingham's AWERB is required to mobilise institutional expertise and resources in order to promote good animal welfare and humane science by ensuring that the use of protected animals is justified. The process should ensure that proper account is taken of strategies to identify, and opportunities to apply, appropriate strategies to Replace, Reduce and Refine (the 3R's) in animal breeding and use in experimentation. UK staff undertaking work outside the University must comply with the University's AWERB procedures.

Where staff and students at UNNC and UNM undertake work outside of the UNNC/UNM facilities they have to complete AWERB procedures. Refer to [Appendix A](#) for UNM processes and procedures and [Appendix B](#) for UNNC processes and procedures.

The AWERB should therefore be notified of all proposed research and/or teaching involving protected animals to be undertaken by, or on behalf of the University staff either at this establishment or at an alternative site (including sites outside the UK). Subsequent recommendation by the Chair of the Animal Welfare and Ethical Review Body is required before the Establishment Licence Holder can countersign a Home Office project licence application for formal submission to the Home Office. All animal work not covered by the Animals (Scientific Procedure) Act 1986, requires approval by the AWERB before such work can commence. For more information see [the University Policy](#) and further guidance [here](#).

17. Acknowledgements, Resources and Major Research Funders' Guidance

We acknowledge the use of the following documents in the preparation of this Code:

Animals (Scientific Procedures) Act 1986 <https://www.gov.uk/government/publications/animals-scientific-procedures-act-1986-amendment-regulations>

Biological and Toxin Weapons Act 1974 <http://www.legislation.gov.uk/ukpga/1974/6>

Biological, Toxin and Chemical Weapons, and Radiological or Nuclear Materials: "Do no harm: reducing the potential for the misuse of life science research" (2004) The Royal Society & Wellcome Trust. <https://royalsociety.org/policy/publications/2004/do-no-harm/>

Council for Science and Technology "Universal Ethical Code for Scientists" https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/283157/universal-ethical-code-scientists.pdf

Counter-Terrorism and Security Act 2015 <http://www.legislation.gov.uk/ukpga/2015/6/contents/enacted>

ESRC Research Ethics Framework <http://www.esrc.ac.uk/about-esrc/information/framework-for-research-ethics/index.aspx>

EU Clinical Trials Directive (2001/20/EC) http://ec.europa.eu/health/human-use/clinical-trials/directive/index_en.htm

Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order 2005 <http://www.hmso.gov.uk/si/si2005/20050468.htm>

Genetic Manipulation Approval

- HSE guidance document that supports the Genetically Modified Organisms (Contained Use) Regulations (<http://www.hse.gov.uk/biosafety/gmo/law.htm>)
- ACGM Compendium of Guidance - Guidance from the Health and Safety Commission's Advisory Committee on Genetic Modification (<http://www.hse.gov.uk/biosafety/gmo/acgm/acgmcomp/>)

Health Research Authority – Research Community and Research Ethics <http://www.hra.nhs.uk/research-community/>

Human Fertilisation and Embryology Authority <http://www.hfea.gov.uk/>

Human Tissue Act/Human Tissue Authority , <http://www.legislation.gov.uk/ukpga/2004/30/contents>, <http://www.hta.gov.uk/>

ICH Good Clinical Practice Guidelines (E6) <http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/good-clinical-practice.html>

Innovate UK <https://www.gov.uk/government/organisations/innovate-uk>

Medicines and Healthcare products Regulatory Agency
<https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency>

Mental Capacity Act (2005) <http://www.legislation.gov.uk/ukpga/2005/9/contents>

MRC Ethics Series 'Personal Information in Medical Research (2000)
<http://www.mrc.ac.uk/documents/pdf/personal-information-in-medical-research/>

NHS Research & Development Forum <http://www.rdforum.nhs.uk>

Office of Research Integrity (ORI) - US Department of Health and Human Sciences - Model Policy for
for
'responsible research – Managing health & safety in research: guidance for the not-for-profit sector'
<http://www.iosh.co.uk/ushaguide>

Responding to Allegations of Scientific Misconduct <https://ori.hhs.gov/sample-policy-procedures-responding-research-misconduct-allegations>
Prevent Duty Guidance: for England and Wales
https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445977/3799_Revised_Prevent_Duty_Guidance_England_Wales_V2-Interactive.pdf

Team Science; <https://acmedsci.ac.uk/policy/policy-projects/team-science>

The Concordat to Support Research Integrity (2019)
<https://www.universitiesuk.ac.uk/topics/research-and-innovation/concordat-research-integrity>

The Wellcome Trust guidelines for researchers <https://wellcome.ac.uk/funding/guidance/guidelines-good-research-practice>

UK Anti-terrorism, Crime and Security Act (ATCSA) 2001
<http://www.legislation.gov.uk/ukpga/2001/24/contents>

UK Chemical Weapons Act 1996 <http://www.legislation.gov.uk/ukpga/1996/6/contents>

UK Data Protection Act (2018) <http://www.legislation.gov.uk/ukpga/2018/12/contents/enacted>

UK Policy Framework for Health and Social Care Research <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/>

UK Research Integrity Office (UKRIO) <https://ukrio.org/>

18. Definitions

Adverse event:

Any untoward or unexpected occurrence in a research participant which may not necessarily have a causal relationship with the research procedures.

Chief Investigator (clinical research only):

The authorised health professional, whether or not they are an investigator at any particular site, who takes primary responsibility for the conduct of the trial.

Covert Research:

Covert methods of research involve the researcher concealing their real role and identity and information about the research being withheld. The people being studied are not fully informed about the research. There are different types of covert research and these can include concealment, misrepresentation, and camouflage.

Informed Consent

A study participant's willingness and voluntary undertaking of participation in a research study after having been informed of all aspects of the study that are relevant to their decision to participate. No details of the study are withheld. Informed consent is usually documented by means of a written, signed and dated consent form.

Investigational Medicinal Product:

A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled in a way different from the approved form or when used for an unapproved indication or when used to gain further information about an approved use.

Occluded Research:

Occluded research is where full information cannot be given to the research participant because this would introduce bias (such as the knowing they were taking a placebo drug), be meaningless (such as in crowd observation) or invalidate the research (such as in psychological experiments where prior disclosure would invalidate the responses).

Principal Investigator:

1. The authorised professional, whether or not they are an investigator at any particular site, who takes primary responsibility for the conduct of the trial.
2. For clinical research, the authorised professional at a particular site, who takes primary responsibility for the conduct of the trial at that site.

Research:

Any form of disciplined inquiry that aims to contribute to a body of knowledge or theory.

Researchers:

Following the UK Research Integrity Office (UKRIO) Code of practice for research (2009), 'researchers' are defined as any people who conduct research, including but not limited to: as an employee; as an independent contractor or consultant; as a research student; as a visiting or emeritus member of staff; or as a member of staff on a joint clinical or honorary contract.

Research Ethics:

The moral principles guiding research, from its inception through to completion and publication of results and beyond – for example, the curation of data and physical samples after the research has been published.

Research Ethics Committee (REC):

A multidisciplinary, independent, body charged with reviewing research involving human participants to ensure that their dignity, rights and welfare are protected. The independence of a REC is founded on its membership, on strict rules regarding conflict of interests, and on regular monitoring of and accountability for its decisions.

Research Sponsor:

An individual, company, institution, or organization which takes responsibility for the initiation, management and financing (or arranging the financing) of clinical and social care research.

Research Participants:

- i) Individuals (humans or non-human animals) who are the recipients of the research interventions or procedures.
- ii) 'Human participants' are defined as including living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and fetuses, human tissue and bodily fluids, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

The World Health Organization Manual (Section XV.2) defines research with human subjects as 'any social science, biomedical, behavioural, or epidemiological activity that entails systematic collection or analysis of data with the intent to generate new knowledge, in which human beings:

- a) are exposed to manipulation, intervention, observation, or other interaction with investigators either directly or through alteration of their environment, or
- b) become individually identifiable through investigator's collection, preparation, or use of biological material or medical or other records.'

The term 'research participant' should also be taken to include any members of the research team or colleagues who volunteer to be subjects of the research.

Research Integrity:

There is no universal definition of research integrity. It can be defined as the professional commitment to conduct all research according to the appropriate legal, ethical and professional frameworks, obligations and standards. There are five core elements of research integrity: honesty, rigour, transparency and open communication, care and respect, and accountability.

19. Contacts

If you have any questions regarding information in the Code of Research Conduct and Research Ethics, please contact the Head of Research Integrity, Mr. Ali Alshukry (Ali.alshukry@nottingham.ac.uk).

For any queries involving research in the NHS or Social Care services please contact the University Research Governance team via email (Sponsor@nottingham.ac.uk).

If you have any questions regarding the Malaysian guidance for the Code of Research Conduct and Research Ethics then, in the first instance, you may contact Associate Professor Steve Stewart-Williams (Steve.Stewart-Williams@Nottingham.edu.my)

If you have any questions regarding the Chinese guidance the Code of Research Conduct and Research Ethics then, in the first instance, you may contact the Chair of the Ethics Committee UNNC Professor Vladimir Brusic (Vladimir.Brusic@nottingham.edu.cn).

Appendix A: University of Nottingham Malaysia (UNM) Guidance

The University of Nottingham's Code of Research Conduct and Research Ethics provides a comprehensive framework for good research conduct and the governance of all research carried out across the University. However, it is understood that researchers at the University of Nottingham Malaysia (UNM) may have to adhere alternative or additional guidelines or conventions. Appendix A outlines some of the adjustments which researchers at UNM may have to consider before commencing their research.

Section 1. Observance of the Code

UNM amendment (i)

All UNM employees, students, visiting and emeritus researchers are expected to adhere to the Code whilst taking into account the additional UNM adjustments and guidance. Where the expected best practice differs between the UK and Malaysia it is expected that the researcher will adhere to whichever of the two sets of guidance presents the highest standards of research ethics or governance. Where there are contradictory definitions of best practice the research should consult with RIS in the UK or the office of the Vice-Provost (Research and Knowledge Exchange) in Malaysia.

Section 2. The Context

UNM amendment (ii)

Some of the UNM adjustments derive from Malaysian Acts of Parliament, e.g. the Personal Data Protection Act (PDPA) 2010. Additionally, other policies are drawn from guidance published by the Malaysian National Institute of Health (NIH) of the Ministry of Health (MOH) and other Malaysian government departments.

Section 3. Research Conduct

UNM amendment (iii)

At UNM researchers are legally bound by the Malaysian Personal Data Protection Act (PDPA) 2010. Although the Malaysian Act is not dissimilar to the UK Data Protection Act (2018), researchers should be aware that there are subtle differences which may need to be addressed. It is likely that inter-campus research may need to satisfy both of these Acts independently.

Section 4. Data

UNM amendment (iv)

At UNM researchers are legally bound by the Malaysian Personal Data Protection Act (PDPA) 2010. However, it is expected that researchers adhere to whichever of the two Acts has the most stringent requirements applicable to their area of research.

UNM amendment (v)

Malaysia has strict controls on the possession, dissemination or publication of a range of materials, e.g. The Film Censorship Act 2002 makes it an offence for an individual to be in possession of "unapproved film or film-publicity material". Researchers should familiarise themselves with the legal framework in Malaysia to ensure that local laws are not broken contravened.

Open Access Publishing

UNM authors have access to the Nottingham ePrints repository for purposes of depositing their research papers. Guidance on using Nottingham ePrints is available from Library Services via the email libraryservices@nottingham.edu.my

It is expected that in 2021-22 the content of Nottingham ePrints repository will be migrated to <https://rdmc.nottingham.ac.uk/>

Section 6. Intellectual property

UNM amendment (vi)

In Malaysia, IP consists of the following categories:

- Patents
- Copyright
- Trademarks
- Industrial designs
- Geographical indications
- Layout designs of integrated circuits

The Intellectual Property Corporation of Malaysia can be contacted for further details of IP rights in a Malaysian context: www.myipo.gov.my

Section 7. Supervision and Leadership

UNM amendment (vii)

Malaysian Good Character Checks: where the research involves participation of children and/or vulnerable adults, the participating organisation via whom the researcher hopes to recruit the study participants may request that the researcher(s) obtain a Certificate of Good Conduct and researchers must be prepared to undertake this. Certificates of Good Conduct may be requested in person directly from the Ministry of Foreign Affairs at Putrajaya. Where the researcher is not residing in Malaysia, such an application can be made through a Malaysian embassy / consulate office overseas.

Section 9. Conflicts of Interest

UNM amendment (viii)

Where there is a potential conflict of interest in research conducted at UNM that falls outside the areas covered by the above policies, this must be discussed with the Vice-Provost (Research and Knowledge Exchange) at the earliest opportunity.

Section 10. Adverse Events

UNM amendment (ix)

The Malaysian Guidelines for Good Clinical Practice state that all serious adverse events being detected or notified should be reported to the sponsor within 2 working days. These immediate reports should be followed up within 7 days with detailed written reports. This detail contrasts slightly with the UK guidance in Part 5 (Regs 32, 33, 34 and 35) of The Medicines for Human Use (Clinical Trials) Regulations 2004: SI 2004/1031, which states: “the investigator shall report any serious adverse event (SAE) which occurs in a subject immediately to the sponsor.”

Section 11. Insurance

UNM amendment (x)

UNM holds insurance policies that provide indemnity for claims against both the University and the individual for:

- Fire and equipment all risk (but not business interruption);
- Employers liability: this covers for claims made for death, injury or disease to any person arising out of and in the course of their employment;
- Public liability: this provides indemnity in respect of claims made for death, injury or disease to persons other than employees or loss or damage to third party property arising out of and during the course of the business;
- Directors and officers insurance: this provides indemnity in respect of legal liability to third parties for breach of professional duty due to negligent act, error or omission in connection with your business.

NB. Each separate policy carries specific inclusions and exclusions. There are currently no insurance policies covering business interruption or clinical trials, both of which are in place at the UK campus.

Section 12. Additional Requirements

UNM amendment (xi)

At UNM all research grants applications and commercial research contracts whose Principal or Chief Investigator is employed by the University must be approved by the Vice-Provost (Research and Knowledge Exchange) or a person or committee nominated by them, e.g. Associate Dean (Research).

UNM amendment (xii)

When proposing to conduct research overseas, researchers from UNM also have a responsibility to inform themselves and be aware of the regulations, local practices and guidelines governing that research within individual countries.

UNM amendment (xiii)

Instead of discussing with the “University Insurance Officer”, researchers at UNM should report to the University Research Integrity and Research Ethics Committee (URIREC). The Chair of URIREC will consult with the relevant Ethics Officer and take the necessary actions to make a decision.

UNM amendment (xiv)

Any medical research that is proposed to be conducted overseas by a UNM researcher must apply to the Science and Engineering Research Ethics Committee (SEREC) or the Faculty of Arts and Social Sciences Research Ethics Committee (FASS REC), and seek favourable ethical opinion to commence the project. The ethics committee will advise on the best course of action and requirements to gain the necessary approval. Researchers of collaborating institutions will have to seek ethical approval from their respective Ethics Committees to commence the proposed project.

UNM amendment (xv)

UNM researchers are responsible for ensuring that in any international research collaborations (including those with researchers at the UK or China campuses) the conduct of the research being undertaken in Malaysia adheres to applicable Malaysian law. Any conflict with other collaborating countries’ laws and practices must be resolved before the research starts.

UNM amendment (xvi)

Malaysia has implemented the Nagoya Protocol via the Access to Biological Resource and Benefit Sharing Act 2017. For a copy of the Act, relevant regulations and other materials, please visit www.myabs.gov.my

Malaysia has strict controls on the possession, dissemination or publication of a range of materials, e.g. The Film Censorship Act 2002 makes it an offence for an individual to be in possession of “unapproved film or film-publicity material”. Researchers should familiarise themselves with the legal framework in Malaysia to ensure that local laws are not broken or contravened.

All research papers (either in the form of the author's final manuscript or the formally-published version/s), where copyright allows, should be deposited in the [Nottingham ePrints](#) repository upon publication or as soon as possible thereafter.

Researchers who are in doubt should seek advice and clarification from the URIREC.

Section 15. Research Misconduct

UNM amendment (xvi)

Where a student, research participant or member of the public has concern about the conduct of research at UNM they should communicate the matter to the supervisor of the research project at the earliest opportunity. If the concern persists or is unresolved, the matter should report to the URIREC. The Chair of URIREC will consult with the relevant Ethics Officer and make a decision on the best action to resolve the matter.

Section 16. Ethics Committees

UNM amendment (xvii)

In Malaysia, the coordination of medical research is carried out through the National Medical Research Register (NMRR) with decisions on project ethics approval being ultimately taken by the Ministry of Health (MOH) Medical Research and Ethics Committee (MREC).

Section 16.3. Ethical review and processes

UNM amendment (xviii)

Medical or clinical research involving Malaysian government hospital resources, staff, patients and biological materials or data derived from them and ALL clinical research involving the use of IMPs or medical devices on human participants must be carried out through the Malaysian National Medical Research Register (NMRR) with decisions on project ethics approval being ultimately taken by the Ministry of Health (MOH) Medical Research and Ethics Committee (MREC). Also, any research involving resources, staff, patients and biological materials or data derived from them will also require approval typically from the Medical Director of each government hospital involved.

All investigators wishing to carry out medical or clinical research in Malaysia are required to undergo training in Good Clinical Practice (GCP) leading to certification prior to involvement in clinical trials. Such training courses must be approved by the National Committee for Clinical Research (NCCR).

Medical or clinical research NOT involving the use of an Investigational Medicinal Product (IMP) or medical device and involving the participation of healthy volunteer research subjects only is reviewed by MREC or the University's Medical School Research Ethics Committee. Any research carried out on Malaysian MOH premises or with the assistance of an MOH grant must be reviewed by MREC and must also adhere to the Malaysian Guidelines for Good Clinical Practice (<http://www.nccr.gov.my/index.cfm?menuid=6&parentid=17>).

UNM amendment (xix)

Any medical or clinical research taking place in Malaysia that requires a Clinical Trial Import License (CTIL) and/or Clinical Trial Exemption (CTX) must be registered with the NMRR. The following categories of products require a CTIL:

- (i) A product (including placebo) which is not registered with the Malaysian Drug Control Authority (DCA).
- (ii) A product with a marketing authorisation but being used in an unapproved manner.
- (iii) A "traditional product" with a marketing authorisation being used for an unapproved indication/therapeutic claims for clinical trial purpose.

For further information consult the Guidelines for Application of Clinical Trial Import Licence and Clinical Trial Exemption in Malaysia (<http://www.nccr.gov.my/index.cfm?menuid=10&parentid=17>).

UNM amendment (xx)

Research taking place in Malaysia that may cause pain, suffering, distress or lasting harm to animals should be approved by an Animal Care and Use Committee (ACUC). The Institute for Medical Research (IMR) ACUC is able to review proposals submitted by external researchers.

The use of protected animals in either research or teaching conducted by, or on behalf of, University of Nottingham staff that may cause pain, suffering, distress or lasting harm should be approved by the Animal Welfare and Ethical Review Body (AWERB) based at the UK campus. This applies to animal work undertaken in Malaysia. Other similar committees do exist in Malaysia: however, ALL activities involving animal work of this nature should be approved via the University of Nottingham AWERB to ensure that appropriate standards are in operation across all University sites.

NOTE:

A protected animals are defined in Section 1.4 of the Guidance to the UK Animals (Scientific Procedures) Act 1986)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/291350/Guidance_on_the_Operation_of_ASPA.pdf

Section 19. Contacts

UNM amendment (xxi)

If you have any questions regarding the Malaysian guidance for the Code of Research Conduct and Research Ethics then, in the first instance, you may contact Associate Professor Steve Stewart-Williams (email: Steve.Stewart-Williams@Nottingham.edu.my).

More information about SEREC and training requirements can be accessed here:

<https://moodle.nottingham.ac.uk/course/view.php?id=49248>. More information about FASS REC can be accessed here: <https://moodle.nottingham.ac.uk/course/view.php?id=49539>

Appendix B: University of Nottingham Ningbo China (UNNC) Guidance

The University of Nottingham's Code of Research Conduct and Research Ethics provides a comprehensive framework for good research conduct and the governance of all research carried out across the University. However, it is understood that researchers at the University of Nottingham Ningbo China (UNNC) may have to adhere to alternative or additional guidelines or conventions.

Section 1. Observance of the Code

UNNC amendment (i)

All UNNC employees, students, visiting and emeritus researchers are expected to adhere to the Code. At the same time, the researchers must take into account the additional UNNC adjustments and guidance. Where the expected best practice differs between the UK and China it is expected that the researcher will adhere to whichever of the two sets of guidance presents the highest standards of research ethics or governance. Where there are contradictory definitions of best practice the research should consult with RIS in the UK or the Chair of the Research Ethics Committee at UNNC.

Section 2. The Context

UNNC amendment (ii)

China has strict controls on the possession, import, dissemination, or publication of a range of materials, regulated by the laws and societal norms. Some of the UNNC adjustments are dictated by the unique cultural and societal norms practiced in China. Researchers should familiarise themselves with the legal framework and societal norms in China to ensure that local laws and norms are not broken or contravened. Some areas of research ethics are not covered by the specific Chinese legislations and regulations. In such situations the University of Nottingham UK rules and regulations will be used as guidance for research conduct and research ethics in UNNC.

Section 3. Research Conduct

UNNC amendment (ii)

Although UNNC researchers will follow both the UNUK and UNNC codes of research conduct, researchers should be aware that there are some specific Chinese contextual issues which may need to be addressed. The inter-campus research must satisfy both codes of conduct and rules and must obtain separate ethical approval from both campuses.

UNNC amendment (iv)

UNNC researchers are required to complete compulsory training in research integrity and ethics conducted regularly at UNNC. The members of the UNNC Research Integrity and Ethics Committee will undergo additional training. Additional guiding principles related to the research ethics conducted in China may be found at AAHRPP and SIDCER.

AAHRPP: <https://www.aahrpp.org/>

SIDCER: <https://www.who.int/sidcer/en/>

Section 4. Data

UNNC amendment (iv)

In China, the Civil Law provides that natural person's data are protected by law. The principal legislation providing for data protection includes the Cybersecurity Law of the People's Republic of China (implemented on June 1, 2017), the Data Security Law (implemented on September 1, 2021) and the Personal Information Protection Law of the People's Republic of China (issued on April 29, 2021, under review as of October 2021). Any research at UNNC must be consistent with the provisions of these laws. When researchers collect secondary data from any third party (e.g. commercial or public entities that collect primary data) supporting documentation (e.g. the contract or description on how the third party collects data) should be available to justify that the third party's

data collection and the data usage by the researchers follow the Civil Law of China. Scientific data requirements in China should adhere to the "Regulation on Scientific Data" (General Office of the State Council of PRC, 17/03/2018) policy. Unless otherwise mandated by the conditions of project funding, data generated in projects funded by the Chinese government sources shall follow open access policy and shall be deposited with a suitable UNNC repository before being sent out of China.

UNNC authors have access to the outputs module of Pure for purposes of depositing their research papers. Guidance on using Pure is available from the Research Office via the email UNNCRIS@nottingham.edu.cn. Guidance on metadata, copyright, and licensing of research papers in Pure is available from the Library via the email publications@nottingham.edu.cn

Section 5. Publications and Authorship

UNNC amendment (v)

All research papers and accompanied data sets (either in the form of the author's final manuscript or the formally-published version/s), where copyright allows, should be deposited in the Nottingham ePrints repository upon publication or as soon as possible thereafter, preferably within one month from the date of publication

Section 6. Intellectual Property

UNNC amendment (vi)

Intellectual property in China is regulated and protected by the country's laws and regulations. The areas governed by these laws and regulations include patents and designs, copyright, trademarks, contracts, and unfair competition. Protection of geographic indication may be done through certification or collective trademarks. Plant breeders can protect their rights to new varieties of plants by registration in China. The researchers should practice highest standards of protection of IP rights of others while conducting their research. Further details on IP laws and policies in China are available at the China National Intellectual Property Administration website: <http://english.sipo.gov.cn/lawpolicy/index.htm>

Section 7. Supervision and Leadership

UNNC amendment (vii)

UNNC has adopted guidelines for the supervision of research undertaken by staff and students in accordance with requirements prescribed from time to time by the Senate and as specified in the Quality Manual for Staff and Students (<http://www.nottingham.ac.uk/quality-manual/>). The quality manual includes regulation specific to the UNNC.

Section 9. Conflicts of Interest

UNNC amendment (viii)

Where there is a potential conflict of interest in research conducted at UNNC that falls outside the areas covered in section 8 of this code, this must be discussed with the UNNC research ethics committee chair at the earliest opportunity.

UNNC amendment (ix)

Due to the widespread social practice of gift giving in China, researchers are allowed to give participants souvenirs and other simple gifts according to the current anti-bribery policy (see <http://www.nottingham.ac.uk/governance/documents/anti-bribery-policy.pdf>).

Section 12. Additional requirements

UNNC amendment (x)

When proposing to conduct research overseas, researchers from UNNC also have a responsibility to inform themselves and be aware of the regulations, local practices and guidelines governing that research within individual countries.

UNNC amendment (xi)

Researchers at UNNC should inform their respective Head of School/Department or the Research Group of plans to conduct any research outside of People's Republic of China.

UNNC amendment (xii)

UNNC researchers are responsible for ensuring that in any international research collaborations (including those with researchers at the UK or Malaysia campuses) the conduct of the research being undertaken in China adheres to applicable UNNC rules including research ethics review procedures and Chinese laws and rules. Any conflict with other collaborating countries' laws and practices must be resolved before the research starts.

If the researcher/s is/are in doubt they should seek advice and clarification from the Chair of their local ethics committee.

Section 15. Research Misconduct

UNNC amendment (xiii)

Where a student, research participant or member of the public has concern about the conduct of research at UNNC they should communicate the matter to the supervisor of the research project at the earliest opportunity. If the concern persists or is unresolved, the matter should be referred to the relevant Head of School or Head of Research Group for resolution. In the unlikely event that the concern remains beyond this, or that the Head of School has a conflict of interest, then the matter should be referred to the Dean of Faculty and the Vice-Provost (Research and Knowledge Exchange) for advice.

Section 16.3.7. Research involving the use of animals

UNNC amendment (xiv)

The use of protected animals in either research or teaching conducted by, or on behalf of, University of Nottingham staff that may cause pain, suffering, distress or lasting harm should be approved by the Animal Welfare and Ethical Review Body (AWERB) based at the UK campus. This applies to animal work undertaken in China. Other similar committees may exist in China, however ALL activities involving animal work of this nature should be approved via the University of Nottingham AWERB to ensure that appropriate standards are in operation across all University sites.

NOTE:

A protected animals are defined in Section 1.4 of the Guidance to the UK Animals (Scientific Procedures) Act 1986)

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/291350/Guidance_on_the_Operation_of_ASPA.pdf

Section 19. Contacts

UNNC amendment (xv)

If you have any questions regarding the Chinese guidance the Code of Research Conduct and Research Ethics then, in the first instance, you may contact the Chair of the Ethics Committee UNNC Professor Vladimir Brusic (Vladimir.Brusic@nottingham.edu.cn)

Country contextual issues in China

UNNC amendment (xvi)

In some cases, researchers may obtain verbal or electronic consent instead of written consent. However, researchers should provide strong justification and explain this strategy in their ethical review applications. If researchers study vulnerable groups such as children or UNNC students, then written consent forms must be obtained.