Code of Research Conduct and Research Ethics

Foreword by Pro-Vice Chancellor Research

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

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Overview

1. To Whom, and to What, does the Code apply?

The University of Nottingham requires all staff and students engaged in research to maintain the highest standards of rigour and integrity in the conduct of that research. This Code of Research Conduct and Research Ethics provides a framework for the governance of all research throughout the University and requires that all researchers adhere to the highest standards of performance and 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 academic staff have freedom within the law to question and test received wisdom, and to put forward new ideas and controversial and unpopular opinions without placing themselves in jeopardy of losing their jobs or privileges.

The Code applies to all UK employees, students, visiting and emeritus researchers, whether they are working on the University's premises or elsewhere. The Code applies to the University of Nottingham's International Campuses (Ningbo China, UNNC and Malaysia Campus, UNM (formally known as University of Nottingham Malaysia Campus until May 2019) but it is understood that researchers at UNNC/UNM may have 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 protocol may differ. As a general rule, where the expected best practice differs between the UK and Malaysia & 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.

The University expects all of its staff and students to follow the ethical behaviours 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, irrespective of how it is funded.

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

2. The Context

This Code takes reference from and follows both the Universities' UK Concordat to Support Research Integrity and UK Research Integrity Office (UKRIO) Code of Practice for Research that was written on behalf of the University sector and provides a basis for the conduct of all research in academia. The UK Research Integrity Office (UKRIO) is an independent advisory body, offering advice and guidance on the good practice of research and how to address misconduct in research. It is hosted by Universities UK and funded by a range of stakeholders including the funding councils, the UK Departments of Health and the research councils.

The Code links to and operates in conjunction with other University policies and procedures (outlined on the Human Resources website) that form part of contracts of employment as well as the Quality Manual (http://www.nottingham.ac.uk/quality-manual/). Some policies derive from Acts of Parliament, such as Health and Safety at Work, Data Protection 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 Research Governance Framework for Health and Social Care. 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 project. 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 a definition of, and procedures for dealing with, allegations of research misconduct. These are linked to the University's staff and student disciplinary procedures and procedures on public interest disclosure.

The Code and its implementation are reviewed on an annual basis by the University's Research Ethics Committee (UREC) and on a tri-annual basis by consultation across the institution. These reviews take into account changes and recommendations from external research funders, Acts of Parliament and other legislations. All reviews are undertaken by the University's Research Ethics Committee and coordinated by Research and Innovation.

Research Conduct

3. Foundations and Specific Requirements for Research Practice

Everyone involved in research in the University owes a duty of accountability to society, to their profession, to the University, to all participants in the research and to its funders. 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.

Researchers must be honest and lawful in respect of their own actions in research and in their responses to the actions of other researchers. This applies to the whole range of research work, outputs and deliverables, including applying for funding, experimental design, generating and analysing data, publishing results, and acknowledging the direct and indirect contribution of colleagues, collaborators and others. Plagiarism, deception or the fabrication or falsification of results shall be regarded as research misconduct and a serious disciplinary offence. Researchers should declare and manage any real or potential conflicts of interest

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, and discussion of these should be included within the Personal Development and Personal Review process for academic staff or training plans for students.

Guidelines for the project management, costing and pricing and authorisation of research proposals with external funders can be found on the Research and Innovation workspace. In addition Research staff -- particularly research team leaders and Chief/Principal Investigators -- must take responsibility for:

3.1 The ethical basis and design of their research projects. Researchers must ensure that research projects are ethically sound and have received the approval of the relevant ethics committee(s) and all relevant statutory regulatory authorities before they commence;

3.2 The safety of all involved in the research process, ensuring that the research is carried out in accordance with health and safety policies and legislative requirements;

3.3 Ensuring that research is conducted in a suitable working environment with appropriate equipment and facilities;

3.4 The probity of the financial management of all research projects, and for seeking to provide the optimum value for the public or private funders who have invested in them including effective project management to agreed project plans and appropriate quality standards, as well as the timely delivery of any scheduled tangible outcomes;

3.5 Management of research data in accordance with the Data Protection Act 2018 and any other legal provisions, conditions and guidelines that may apply to the handling of personal information (see 4.1, below) (Refer to Appendix A for UNM guidance and Appendix B for UNNC guidance);

3.6 Undertaking professional development appropriate to the research;

3.7 Ensuring that all personal records of research progress, including authorised laboratory books, are maintained to the recommended or required standards, and that the falsification of results does not occur. Laboratory books must be signed and dated by the researcher, and signed off by the supervisor;

3.8 Ensuring confidentiality in order to achieve protection of intellectual property rights where appropriate;

3.9 Ensuring that research findings are suitably disseminated;

3.10 Except in the case of covert research that has been appropriately approved, ensuring that research participants participate in a voluntary way, free from any coercion;

3.11 Avoiding harm to participants and minimising any adverse effect that the research may have on people, animals and the natural environment and property.

4. Data

Research data is data which is collected, observed, or created for purposes of analysing 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 terms of relevant University policies such as General Data Protection Regulation (GDPR) (UoN GDPR Workspace) Research Data Management (RDM) (UoN RDM Web) and Secure Data Handling (UoN Information Security Workspace) policies, and should adhere to any funder requirements.

Personal data is any data by which an individual could be identified, this includes data which is considered 'special category data' by the GDPR, particular care has to be taken when handling **Special Category Personal data** 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).

Commercially-sensitive data must also be handled in accordance with the Secure Data Handling Policy (available at UoN Information Security Workspace).

It is recommended that researchers familiarise themselves with University guidance which interprets the application of the Act 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 with as few restrictions as possible in a timely and responsible manner; and as such published research papers should include a short statement describing how and on what terms any supporting research data may be accessed. In case 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.

Some central issues for researchers are:

4.1 Personal Data

4.1.1. Only personal information pertinent to the research should be collected; valid grounds for data collection and processing must be identified

4.1.2. Special Category data under GDPR must have a further lawful basis for processing

4.1.3 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.

4.2 Research Data

4.2.1 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 UoN RDM policy and must be accompanied by appropriate metadata or documentation.

4.2.2 Research data deposited for archive is retained and preserved for a period at least as long as that required by any funder or regulator of the research, or as set out in the University's Records Retention Schedule

4.2.3 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

4.2.4. Data should be stored in a managed environment such as O365 to protect the data against data loss and corruption, unauthorised access and modification, and to comply with relevant legal, ethical, regulatory, contractual and intellectual property protection obligations

4.3 Confidentiality
4.3.1 Individual participant 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

4.3.2 Participant confidentiality should be ensured by using anonymisation techniques standard within the research field. When data cannot be fully anonymised, it should be pseudonymised as far as possible

4.4 Open Access Publishing
The University's Open Access policy applies to all members of staff employed by the University at all campuses

4.4.1 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

4.4.2 All research papers (either in the form of the author's final manuscript or the formally-published version), where copyright allows, should be deposited in the Research Information System (RIS) upon acceptance by the publisher or as soon as possible thereafter. For UNM and UNNC these should be deposited in the Nottingham ePrints repository upon publication or as soon as possible thereafter;

4.4.3 Where available, researchers should take advantage of opportunities to publish their work in an open access form offered by journal publishers and can make use of research grants and/or the central Open Access publication fund, in order to pay open access publication fees

Full details of the University's Open Access policy can be found on the workspace Open Access for Research

4.5 Data Sharing
Sharing data supports the integrity of your research by allowing your data to be independently validated and tested. It also ensures that you are complying with mandates set by some publishers and funders

4.5.1 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

4.5.2 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 an ethics committee or the data asset owner

4.5.3 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

4.5.4 Personal data should only be shared in line with the individual's expectations and using appropriate safeguards, for example, the use of anonymisation or pseudonymisation techniques

4.6 Criminal Offences concerning obtaining, possessing or publishing information
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.

Further guidance can be found in the UUK document Freedom of Speech on Campus: rights and responsibilities in UK Universities (2011) https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2011/freedom-of-speech-on-campus.pdf
If any member of staff wishes to seek advice on the application of this or similar legislation they should contact their HR Business Partner (HRBP) in the first instance. A list of HRBPs can be found at http://nottingham.ac.uk/hr/aboutus/business-partnering.aspx.

Refer to Appendix A for details on how this should be applied on UNM campus.

4.7 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.

5. Publications

For the purposes of the Code, publications include reports and technical reports in printed and electronic form, where these are 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 papers in refereed journals. 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 A publication must contain appropriate reference to the contributions made by all participants in the relevant research;

5.2 The research funder should be notified in advance when research might be published, publicised or disseminated;

5.3 Any person who has not participated in a substantial way in conceiving, executing or interpreting at least part of the relevant research is not to be included as an author of a publication derived from that research;

5.4 In addition to meeting the requirements of the points above, an author must ensure that the work of research students, research assistants, research officers, and technical officers is recognised in all publications derived from research to which they have made a contribution;

5.5 A publication which is substantially similar to other publications derived from the same research must contain appropriate reference to the other publications;

5.6 A researcher who submits substantially similar work to more than one other publisher should disclose that fact to the publishers at the time of submission;

5.7 Publication and dissemination of work electronically or on the Web should be treated with the same degree of integrity as every other form of publication;

5.8 Individuals who are or have been the participant of the research should not be identified or identifiable in any publication. Measures should be taken to disguise the identity of research participants unless explicit consent is given by them for revealing their identity.

In addition to publications, all external communications, whether through websites, e-bulletins, press releases, media briefings, or events should be undertaken with the core principles of openness, transparency and accountability.

6. Intellectual Property

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

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, art work, 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 trade marks

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 the Business Engagement and Innovation Services workspace:.
https://workspace.nottingham.ac.uk/display/BEIS/Intellectual+Property

Refer to Appendix A for UNM guidance and Appendix B for UNNC guidance on intellectual property

7. Supervision

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 (http://www.nottingham.ac.uk/quality-manual/). 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.

All supervisors must observe and undertake the responsibilities set out in these guidelines.

A person must decline appointment as a supervisor unless he/she expects to be able to discharge the responsibilities set out in these guidelines.

7.1 Lone Working

Where research involves lone working or contact with research participants outside of the University premises a lone-working policy should be set up. Where possible, lone-working is to be avoided. 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). Guidance on lone-working can be found on the following workspace

7.2 Disclosure and Barring Service

The DBS was established 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 Disclosure and Barring check (DBS) 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.

Please note that only organisations entitled to ask an exempted question under The Rehabilitation of Offenders Act 1974 (Exceptions) Order 1975 are eligible to request DBS checks. These organisations must either be registered directly with the DBS or apply through an organisation that is already registered an Umbrella Body). The University's guidance on the Protection of Children and Vulnerable Adults can be found here.

8. Conflicts of Interest

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 it either 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. See: http://www.nottingham.ac.uk/hr/guidesandsupport/universitycodesofpracticeandrules/externalwork.aspx

The University has a policy on Conflicts of Interest, Gifts and Hospitality. This policy 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. See: (http://www.nottingham.ac.uk/hr/guidesandsupport/universitycodesofpracticeandrules/conflictsofinterest,giftsandhospitality.aspx

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 Director of Research and Graduate Services at the earliest opportunity. Refer to Appendix A for how this applies to UNM and Appendix B for how this applies at UNNC. 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 Director of Research and Graduate Services can refer any potential conflict of interest to the Pro-Vice Chancellor Research.

9. 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.

For clinical/medical research where ethical approval has been sought and granted from an NRES Research Ethics Committee there are specific reporting requirements for serious adverse events. In addition to these, specialised reporting requirements and actions apply in relation to clinical trials involving the use of Investigational Medicinal Products that are regulated by the 'Medicines for Human Use (Clinical Trials) Regulations 2004,' the UK implementation of the EU Clinical Trials Directive 2001/20/EC and the International Conference of Harmonisation's Good Clinical Practice guidelines. Standard Operating Procedures available on the Research Governance Workspace Pages (https://workspace.nottingham.ac.uk/display/ResG/Introduction) give instructions on how to meet these reporting requirements. Refer to Appendix A for variations in application on the UNM campus.

10. Insurance

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

10.1 Property and business interruption;

10.2 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;

10.3 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;

10.4 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

10.5 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, Channel Islands and the Isle of Man.

Details can be found on the Commercial Services web page or by contacting the University Insurance Officer. See: http://www.nottingham.ac.uk/fabs/procurement/insurance/insurance.aspx. Refer to Appendix A for details of the UNM policy.

11. Additional Requirements

Any special standards of work performance and ethical conduct that are imposed by law or by the University in relation to particular categories of research are deemed to be included in this Code in its application to persons engaged in that research in the University. Project managers have a responsibility to inform staff about the implications and ensure that they agree to and accept the terms.

All research grants applications and commercial research contracts whose Principal or Chief Investigator is employed by the University must be approved by Research and Graduate Services and the Head of School or equivalent unit (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.

11. 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.

For non-medical research at the University, ethical opinion must also be obtained via the usual route for your School. In addition to this, 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. Both countries' laws and practices 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).

11.2 Multi-Funder Requirements

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.

12. Procedures for Dealing with Allegations of Research Misconduct

Research misconduct means fabrication, falsification, plagiarism or deception in proposing, carrying out or reporting progress or results of research and deliberate, dangerous or negligent deviations from accepted practice in carrying out research and from this Code of Conduct, whether or not it causes harm. It includes failure to follow established protocols if this failure results in unreasonable risk or harm to humans, animals or the environment. It also includes assisting in misconduct by other researchers by collusion in, or concealment of, any of the actions listed above. It does not include honest error or honest differences in design, execution, interpretation or judgement in evaluating research methods or results or misconduct (including gross misconduct) unrelated to the research process. An allegation of research misconduct is a serious and potentially defamatory action and could lead to a threat (or even the instigation) of legal proceedings. Consequently for the protection of the complainant and of the party against whom the allegations are made, all enquiries (including the formal investigation, if any) should be conducted on a basis of strict confidentiality (wherever possible) as well as of integrity and non-detriment so that neither party should suffer solely as a consequence of the allegation being made.

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 Graduate Services will act in an advisory capacity to support the process in cases of academic research misconduct.

Where a student, research participant or member of the public has concern about the conduct of research 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 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 Director of the Research and Graduate Services for advice (Refer to Appendix A [UNM] or Appendix B [UNNC] for referrals on the international campuses). Where a member of staff has concerns about the conduct of research this should also, in the first instance, be communicated to the supervisor of the research project. Where this is not possible, staff are reminded that the University's Whistle Blowing Policy gives protection to employees to disclose confidential information about malpractice in the workplace, whether carried out by other employees or the employer. In such an instance, concerns should be raised to the relevant Head of School. Where this is not possible, the matter should be referred to the Chair of the University's Research Ethics Committee.

Allegations of research misconduct that cannot be informally resolved are participant to formal investigation and may be dealt with in accordance with the provisions of University procedures:

- Disciplinary procedure for all staff (except O&F) (http://www.nottingham.ac.uk/hr/guidesandsupport/performanceatwork/disciplinaryprocedures/documents/disciplinary-procedure.pdf);

- The Code of Discipline for Students: http://www.nottingham.ac.uk/governance/documents/code-of-discipline.pdf

- Whistle Blowing Policy
http://www.nottingham.ac.uk/governance/otherregulations/whistleblowing/index.aspx

The University is required to report annually through Audit Committee whether any issues of research misconduct have arisen concerning any Research Council funded researchers. Schools should report this to Research and Graduate Services.

Research Ethics

13. Origins of Research Ethics

Consideration of ethical issues has long been a feature of medical research and most notable has its origins in the *Nuremberg Code 1947*, following the trials of the Nazi war criminals. It is the most important document in the history of the ethics of medical research and the first of its kind to ensure the rights of participants. The Nuremberg Code includes such principles 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 voluntary code covering the conduct of social-economic research in Europe.

14. Ethics Committees

The *Declaration of Helsinki* enunciated the principle of independent assessment of experimental procedures involving human participants. In full this section (B13) reads:

"The design and performance of each experimental procedure involving human participants should be clearly formulated in an experimental protocol. This protocol should be submitted for consideration, comment, guidance and where appropriate, approval to a specially appointed ethical review committee, which must be independent of the investigator, the sponsor or any other kind of undue influence. This independent committee should be in conformity with the laws and regulations of the country in which the research experiment is performed. The committee has the right to monitor ongoing trials. The researcher has the obligation to provide monitoring information to the committee, especially any serious adverse events. The researcher should also submit to the committee, for review, information regarding sponsors, institutional affiliations, other potential conflicts of interest, and incentives for subjects.''

The National Health Service 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 National Research Ethics Service (NRES). NHS RECs review and give ethical approval to all research involving the NHS and/or the use of investigational medicinal products or devices (Refer to Appendix A for UNM processes).

14.1 University Ethics Committees

As the importance of ethical scrutiny of research projects has grown, the value of having ethics committees in other institutions has been recognised. The University has a central University Research Committee that is responsible for all School Research Ethics Committees.

The purpose of ethical approval within the University is positive and threefold:

i) The University is committed to following good ethical practice, as a principle in itself and as a means by which the public can be assured of confidence in the work of staff and students of the University.

ii) The provisions for ethical review and approval assist researchers in the identification of ethical issues and to address them in the structuring of research protocols. 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 approval process acts as a safeguard to researchers, supervisors and students who can be confident of the ethical propriety of their project once it has been approved.

15. Need for Ethical review and the review process

Ethical review (and approval) is required where the research involves the participation of human participants (participants, see Section 17 for definition), their data and/or their tissue. 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 15.6 – 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.

Responsibility for ensuring proper ethical review lays with the Chief or Principal Investigator reporting on behalf of co-investigators through his/her Head of School, and involving the University Ethical Review Process for licensed work as appropriate. The Research Governance Manager will monitor compliance and develop best practice through the University.

In addition to complying with the University's internal policies on the governance of Research Ethics Committees, each School must ensure that external systems are employed to review the ethical implications of research undertaken by its academic and research staff and students before any research commences. Normally, external research sponsors will not release funds unless they receive evidence that approval has been given by the relevant research ethics committee.

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 approval of one or more ethics committees. If there is any doubt about the need for ethical approval in relation to their proposed research, staff should seek advice from their School Research Ethics Officer.

15.1 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.

15.2 Non-medical research

Non-medical research involving human participants are reviewed by internal review via the individual School's ethics committee or through its agreed designated reviewing process through another School's committee. In exceptional circumstances when a School committee is unable to agree on ethical review such cases are referred to the University's Ethics Committee.

15.3 Medical or clinical research

Medical or clinical research NOT involving the use of an Investigational Medicinal Product (IMP) or medical device and involving the participation of healthy volunteers only is reviewed by the Medical School Research Ethics Committee.

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 must be approved by a UK Ethics Committee Authority registered ethics committee. These are part of the Health Research Authority. Also, any research involving resources, staff, patients and biological materials or data derived from them will also require approval from the R&D Office of each NHS Trust involved. Standard Operating Procedures are available on the Research Governance Workspace (Refer to Appendix A for UNM procedures and processes).

15.3.1 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. Standard Operating Procedures available on the Research Governance Workspace pages give instructions on how this is done. Furthermore, the University's Research and Graduate Services office checks and maintains records of ethical approvals in relation to the grants it administers.

15.3.2 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. Standard Operating Procedures available on the RGS web page under Research Governance give instructions on how to do this.

15.4 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). There is legislation specific to research involving vulnerable adults and children. Researchers must ensure that they are familiar with the requirements of these legislations before designing their research. Advice can be sought from the Research Governance Manager.

15.5 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.

All such research *must* be ethically reviewed by a School ethics committee. The choice of committee depends on the nature of the research and whether the research is of a medical basis or not. Where the research is to investigate a medical condition then ethical approval as in Section 9 must be sought. Where the research is non-medical ethical approval advice can be sought from the University Ethics Committee at any time to inform any sub-committee's decision.

15.5.1 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.

15.5.2 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.

15.5.3 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.

15.6 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. See page 88 of the Guidance available at this link:

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

The University of Nottingham's local Animal Welfare and Ethical Review Body (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 animal production and use (the 3R's). No work on animals is undertaken at UNNC and UNM. However, where staff and students at those two campuses undertake work outside of the UNNC/UNM facilities they have to complete AWERB procedures as for UK staff undertaking work outside the University. Refer to Appendix A for UNM processes and procedures and Appendix B for UNNC processes and procedures.

The Animal Welfare and Ethical Review Body should therefore be notified of all proposed research and/or teaching involving protected animals to be undertaken by, or on behalf of 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 being required before the Establishment Licence Holder can countersign a Home Office project licence application for formal submission to the Home Office; or for animal work not covered by the Animals (Scientific Procedure) Act 1986, approval by the AWERB before such work can commence.

See: http://www.nottingham.ac.uk/animalresearch/policy/policy.aspx

16. Resources and Major Research Funders' Guidance

Information relating to the University's Research Ethics Committee including details of School Research Ethics Officers can be found on the workspace:
https://workspace.nottingham.ac.uk/display/ResEth/Research+Ethics+Officers

Where appropriate to the research being undertaken, researchers should refer directly to the following guidance, and any other guidance relevant to the sponsor and/or specific research area. We acknowledge the use of some of the following documents in the preparation of this Code:

NHS Research Governance Framework (2001; second edition: 2005)
http://www.hra.nhs.uk/resources/research-legislation-and-governance/research-governance-frameworks/

MRC Policy and Procedure for Investigating Allegations of Scientific Misconduct (2014)
http://www.mrc.ac.uk/research/research-policy-ethics/allegations-of-research-misconduct/

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

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

AMRC Guidelines on Good Practice in Research
http://www.amrc.org.uk/our-work/good-research-practice

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

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

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

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

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

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

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

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

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

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

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/)

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

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/

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

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

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

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

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

Office of Research Integrity (ORI) - US Department of Health and Human Sciences - Model Policy for Responding to Allegations of Scientific Misconduct
http://ori.hhs.gov/policies/model_policy.shtml

UK Research Integrity Office (UKRIO)
http://ukrio.org/

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

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

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

17 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 he is 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 he is 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.

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 research.

Research Participants:
i) Individuals (humans or 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 foetuses, 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).

18. Contacts

If you have any questions regarding information in the Code of Research Conduct and Research Ethics, please contact the Head of Research Governance, Ms Angela Shone (email:angela.shone@nottingham.ac.uk; telephone +44 115 84 67906) or the Secretary to the University's Research Ethics Committee, Kate Miller (email: research-ethics@nottingham.ac.uk or kate.miller@nottingham.ac.uk; telephone +441158466418).

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 Soma Mitra. (Soma.Mitra@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 Associate Professor, Fillipo Gilard for Research and Knowledge Exchange.

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) (formally known as University of Nottingham Malaysia Campus until May 2019) 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. To whom, and to what, does the Code apply?

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 Transfer) 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.

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

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 from 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 8. 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 Transfer) at the earliest opportunity.

Section 9. 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 10. 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 11. 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 Transfer) 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 inform their respective Head of School / Department of plans to conduct any research outside of Malaysia.

UNM amendment (xiv)
Any medical research that is proposed to be conducted overseas by a UNM researcher must firstly be discussed with the Head of School / Department who may decide to refer details of the research to the Associate Dean (Research) or Vice-Provost (Research and Knowledge Transfer).

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.

Section 12. Procedures for dealing with allegations of 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 be referred to the relevant Head of School 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 Transfer) for advice.

Section 14. 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) Research and Ethics Committee (MREC).

Section 15. Need for Ethical review and the review process

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) 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 is 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 18. 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 Dr Soma Mitra (email: soma.mitra@nottingham.edu.my ; telephone +6 (03) 8725 3433).

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. Appendix C outlines some of the adjustments which researchers at UNNC may have to consider before commencing their research.

Section 1. To whom, and to what, does the Code apply?

UNNC amendment (i)
All UNNC employees, students, visiting and emeritus researchers are expected to adhere to the Code whilst taking 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)
Some of the UNNC adjustments are dictated by the unique cultural norms practiced in China. Due to the lack of the specific Chinese legislations and regulations on research ethics and personal data protection issues, the UNUK rules and regulations will be followed in China.

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. It is likely that inter-campus research must satisfy both codes of conduct and rules, and must obtain separate ethical approval from both campuses.

Section 4. Data

UNNC amendment (iii)
In certain areas where there may be a lack of specific Chinese legal acts and regulations, researchers at the UNNC are expected to adhere to the UK Data Protection Act 2018 applicable to their area of research.

Section 6. Intellectual Property

UNNC amendment (iv)
Regulations do exist in China which cover Chinese intellectual property (e.g. Chinese patent laws and regulations, copyright law, trademarks, contract law, and laws against unfair competition, etc.). For further details of IP Rights in a Chinese context, please visit the following website: http://english.sipo.gov.cn/lawpolicy/index.htm

Section 8. Conflicts of Interest

UNNC amendment (v)
Where there is a potential conflict of interest in research conducted at UNNC that falls outside the areas covered by the above policies, this must be discussed with the UNNC research ethics committee chair at the earliest opportunity.

UNNC amendment (vi)
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 11. Additional requirements

UNNC amendment (vii)
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 (viii)
Researchers at UNNC should inform their respective Head of School / Department of plans to conduct any research outside of People's Republic of China.

UNNC amendment (ix)
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.

Section 12. Procedures for dealing with allegations of research misconduct

UNNC amendment (x)
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 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 15.6 Research involving the use of animals

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 is 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 18. Contacts

UNNC amendment (xi)
If you have any questions regarding the Chinese appendix of the Code of Research Conduct and Research Ethics then, in the first instance, you may contact Dr Fillipo Gilardi, (filippo.gilardi@nottingham.edu.cn) Tel: +86 (0)574 8818 0000 (Ext 8289)

Country contextual issues in China

UNNC amendment (xii)
In some cases, researchers may obtain verbal participant consent instead of written consent. However, researchers should justify 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.