

University Guidance on the Ethical Approval of International Research and Research at International Branch Campuses

Newcastle has seen a significant growth in the amount of collaborative research it undertakes, and this is especially true for research with international partners / research taking place overseas. The University is supportive of these developments as they represent an opportunity to increase the scope, number and impact of the University's research activities; however it should be borne in mind that international research can introduce increased complexities to research governance. This is because the standards, requirements and permissions will often be significantly different to those in the UK and European Economic Area (EEA). This document aims to give guidance and an overall summary of the University's requirements.

Overview

The University has a single [online ethical review form](#) and process for all projects regardless of whether the research project is funded or unfunded, a staff or student project or which area the research is in. The form is made up of a series of areas which the University has identified as high risk; Animals, Health & Social Care, Humans in a non-clinical setting, Data, Environment and International.

The University requires that this form is completed when it is the research sponsor, this can be defined as 'research undertaken by its staff and student body in the University's name which the University is guaranteeing the governance and integrity of'.

In the interests of minimising the administrative burden on PIs the University will sometimes accept other organisations ethical approval in lieu of its own. The most common example of this is projects that have received ethical approval from the National Research Ethics Service (NRES) which approves projects in the NHS. For organisations which the University has a less established relationship with, University ethical approval may be needed in addition to other ethical approvals.

Projects identified as requiring further ethical approval by a University Committee will then be submitted to the relevant ethical review committee for a decision. No research can be started until the correct approval has been granted and all relevant permissions received.

Projects Involving Newcastle Staff Researching Outside the EEA

Projects outside the EEA are likely to require further ethical approval and need to submit a full form. The degree of detail will vary on the project and especially if ethical approval is being sought from another organisation e.g. a local hospital.

The risk factors that the University may be concerned with are:

- The different legal framework and need for permissions
- Variances in cultural attitudes to research and ethical norms e.g. around consent -
Researcher Safety

The most likely route for ethical review is the relevant Faculty ethical review committee.

Projects Involving Collaboration with a Partner outside the EAA

Projects outside the EEA may require further ethical approval. Although Newcastle researchers will be themselves working within the EAA and the processes for managing research are well understood. The risk factors that the University may be concerned with are:

- The handling of sensitive information outside known legal jurisdictions
- The potential purpose of the research
- Issues relating to the funding of the research

The most likely route for ethical review is the relevant Faculty ethical review committee.

Projects undertaken at NUMed Malaysia

The same forms and processes are used as for any other project. There are however important differences:-

- Where legislation is directly referenced in the form, the local equivalent should be checked, where the local standards are less stringent than UK standards the project should be flagged and the differences explained in a full ethics review.
- Animals: Malaysia has no regulations on research involving animals therefore any project involving animal research should be flagged as requiring ethical approval and be sent to the University Ethics Committee. This is regardless of whether permission has been granted locally.
- Humans Clinical: The section 'NHS, Health & Social Care: Facilities, Staff & Patients' should be read in conjunction with the following local Guidelines: [Malaysian Medical Council Ethical Code & Guidelines](#)
Local approval for clinical research will always be required from the local hospital or clinical body and should be submitted to the relevant faculty research committee along with the preliminary form.
- Environment: A list of relevant environmental legislation relevant is available on the [Ministry of Natural Resources and Environment website](#).
- Data: Malaysia is currently implementing the '[Personal Data Protection Act 2010](#)' (PDF:733KB) all data created by the research should be handling in line with it and any ancillary guidance.
- Projects undertaken by members of the staff and student body at NUMed within Malaysia can be classed as local rather than overseas. Provided that the preliminary form is accompanied by a letter from the Supervisor stating that the relevant rules / legislation which will impact on the research project are equivalent to the UK.

Projects undertaken at Newcastle's Campus in Singapore

The same forms and processes are used as for any other project. The differences are similar to those above:-

- Where legislation is directly referenced in the form, the local equivalent should be checked, where the local standards are less stringent than UK standards the project should be flagged and the differences explained in a full ethics review.
- Any research involving animals must be undertaken in line with the '[Animals and Birds \(Care and Use of Animals for Scientific Purposes\) Rules 2004](#)' and other relevant rules outlined by The [Singapore Agri-Food & Veterinary Authority](#) of Singapore. A full ethical approval must still be submitted to the University Ethics Committee.
- The section 'NHS, Health & Social Care: Facilities, Staff & Patients' should be read in conjunction with the [Health Sciences Authority Regulations](#).
Additional permissions should be sought from the Health Sciences Authority. Local approval for clinical research will always be required from the local hospital or clinical body and should be submitted to the relevant faculty research committee along with the preliminary form.
- Environment: Any research undertaken impacting on the Singapore environment must be undertaken according to the [Environmental Protection and Management Act. 1999 \(Rev. 2002\)](#) and other guidance provided by the [National Environment Agency](#).
- Data: All research data in Singapore should be treated in accordance with the '[Personal Data Protection Act 2012](#)'
- Projects undertaken by members of the staff and student body at Newcastle Singapore within Singapore can be classed as local rather than overseas. Provided that the preliminary form is accompanied by a letter from the Supervisor stating that the relevant rules / legislation which will impact on the research project are equivalent to the UK.

The guidance in this document is necessarily non-specific, if you have queries that relate to a particular circumstance or project then please use the below contacts.

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- Faculty of Humanities and Social Sciences: Lorna Taylor (lorna.taylor@ncl.ac.uk)
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- University Research Office: Research Policy, Intelligence, and Ethics (res.policy@ncl.ac.uk)

Links updated Feb 2020