

ETHICS, RESEARCH AND DEVELOPMENT COMMITTEE: PROCESSES AND GUIDELINES





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NC ITALIAN UNIVERSITY

Foreword

The University's research activity is overseen by the University Ethics, Research and Development Committee (UERDC), reporting to the University Senate which oversees all academic matters. UERDC advises the Academic and University Executive Board on strategy; this includes internal policy approvals and the monitoring of research performance

in the whole institution.

Since the Research and Development Committee is a sub-committee of the Academic Board,

its role is to support in matters related to:

i) promote an ethical practice in all faculties

ii) oversee, monitor, coordinate and communicate NC IUL's ethics policies to all staff and

students. This includes providing and organising training, education and continuing

professional development events to disseminate ethical policies.

iii) review all staff and student research studies to ensure they meet NC IUL's ethical codes

(documents in preparation). Staff and students are asked to submit their research proposals to

the Ethics Committee for review, before they start a project.

iv) maintain and develop excellence in research and provide high quality research training in

all subject areas in relation to Quality Assurance frameworks (QAA).

v) suggest and implement strategic plans to promote research, innovation and collaboration

within Faculties and external bodies and professions;

vi) make suggestions and present projects and activities to submit application for research

grants and funding.

The Committee for Ethics, Research and Development will meet at least 4 times a year to



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carry out these duties.



Committee membership

Membership of the Committee for Ethics, Research and Development is formed by:

- 1) the Chair, appointed by the Academic Board;
- 2) the Dean of each Faculty; or
- 3) the Associate Dean of each Faculty;
- 4) external advisers; and
- 5) at least two appointed members from the Student Council.

Notes about Committee Minutes

In line with the University's Freedom of Information (FoI) Policy, the minutes of the meetings will be made publicly available at the earliest convenience. However, commercially sensitive content is removed in accordance with provisions of the Freedom of Information Act. Full minutes are available for staff members only.

Submissions of papers

New policies and initiatives, strategic approaches and any other business with significant implications for the research community must be formally approved by the University Ethics, Research and Development Committee (UERDC). It is strongly recommended that colleagues developing business for consideration by UERDC should invite engagement from/consult with the wider academic community as part of the development process, **prior**





to submission to UERDC.

Once an item of business has been approved by UERDC, communication of the outcome and/or the implementation process will also need to take place via the appropriate research governance within each department.

Guidance on routes for consultation, engagement, dissemination, and implementation

The University's research governance model – i.e. the structure for decision making and accountability – is academic-led. New policies and initiatives, strategic approaches and any other business with significant implications for the research community must be formally approved by the University Ethics, Research and Development Committee (UERDC).

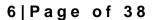
It is strongly recommended that colleagues developing business for consideration by UERDC should invite engagement from/consult with the wider academic community as part of the development process, prior to submission to UERDC. This ensures that items of business for UERDC are focused and informed, and lays the groundwork for subsequent implementation and assimilation of new approaches across the University. A formal committee with a sizeable agenda such as UERDC is not in itself an appropriate forum for broad academic consultation, nor does UERDC conduct consultation/engagement itself: its role is to consider finalised proposals once such processes have taken place. The various options for engagement/consultation are set out below. A summary of the process should be provided for UERDC as part of the item of business so that the Committee can be confident that academic input has been sought at an appropriate level from representatives of the staff which the initiative is going to affect.

Colleagues should decide on an appropriate route for academic engagement/consultation given the nature of the business in hand.

The following options are available:



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a. Faculty Research Groups (staff members within each faculty who are already involved in ethics approvals, research and training activity);

b. Research Forum;

c. A dedicated representative working group e.g. where input will be sought on multiple iterations of an item under development, and/or if specialist knowledge and engagement with detail is required;

d. Preliminary soundings on strategic matters can be sought informally from the UERDC Chair, the Deans and/or the Associate Deans;

More than one route might be adopted as appropriate. Colleagues will need to take into account the following factors:

- i. The significance of the changes proposed;
- ii. The range of people affected;
- iii. The parameters of consultation and the extent to which it is possible/desirable to take account of all shades of opinion;
- iv. Any confidentiality issues;
- v. Whether inter-departmental discussion is needed;
- vi. The level of detail involved does the group circulate papers in advance?

Advance planning will be needed in order to meet the deadlines for established groups or to set up a dedicated working group, and to allow time to assimilate input prior to submitting an item to UERDC. A calendar of meeting dates where these are scheduled annually, including UERDC, can be found via the above web link.

The consultation/engagement process must be led and managed by the project lead rather than relying on the Chairs/Secretaries of the various groups. The project lead should prepare an appropriate level of information for the group in question and make it explicit what actions the group is being asked to take (e.g. in the form of a brief and appropriately tailored cover







sheet if a formal paper is involved).

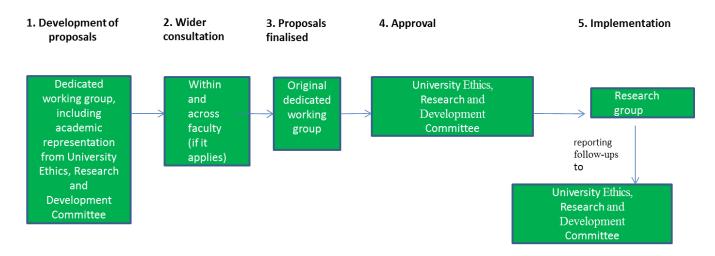
Once an item of business has been approved by UERDC, communication of the outcome and/or the implementation process will need to take place via the appropriate research governance and support groupings. Again, this should be planned in advance, and led and managed by the project lead, rather than the Chairs/Secretaries of the various groups, in order to avoid duplication, misinformation and/or premature action. As part of the advance planning, the project lead should consult informally with the Chairs/Secretaries of the various groups to check that plans are appropriate and ensure everyone understands what has been agreed. Information should be tailored appropriately to the audience in question, making it clear what actions it is being asked to take. The formal passage of minutes between groups should not be relied upon to progress business at an operational level (although copies of individual minutes relating to the item of business might be included for information).

An example of business progression can be found below:

- 1. DEVELOPMENT OF PROPOSALS
 - Dedicated working group, including academic representation from the University Ethics, Research and Development Committee
- 2. WIDER CONSULATION Within and across faculty (if it applies)
- 3. PROPOSALS FINALISED FROM THE ORIGINAL DEDICATED WORKING GROUP
- 4. APPROVAL BY THE UNIVERSITY ETHICS, RESEARCH AND DEVELOPMENT COMMITTEE
- 5. IMPLEMENTATION BY THE DEDICATED RESEARCH GROUP
- 6. Meetings and paper submissions to the UERDC committee in relation to the progression of the proposal (see 'follow-ups in the flow chart below)







The following section will provide additional guidance to ensure a clear and co-ordinated approach within the University for communicating, discussing and responding to significant policy developments relating to research.

Standard University approach for managing the internal information flow

The University Ethics, Research and Development Committee (UERDC) proposes a clear and co-ordinated approach within the institution for communicating, discussing and responding to significant external policy developments relating to research, in order to avoid duplication, misinformation and/or premature action.

The following approach is therefore proposed:

As far as possible, the institutional approach should be agreed in a timely fashion between the UERDC Chair, the Faculty Deans and (if it applies) the Associate Deans, supported by the professional support colleague responsible for leading in that area. Identification of the lead professional support colleague as soon as possible is essential for the effective co-ordination of the University's response. Where external developments involve PhD studentships, the Dean should also be involved. If the external development relates to a new area, the need to





nominate a specific academic lead for the new area should also be considered.

The involvement of the various core research governance structures (i.e., the UERDC and those involved in ethics, research and development) and any interaction between them should be clearly articulated, with reference to the annual schedule of meetings [see academic calendar].

Once an approval has been made the research group has the duty of co-ordinating the circulation of information to the university with an indication of the implementation status at regular intervals. Any queries regarding the agreed approach should be referred to the university research committee.

More specifically, the institutional approach might include:

- Communication of the external policy developments and any subsequent updates across the University;
- Identifying areas to refer for productive discussion at University, Faculty and/or departmental level, and/or amongst professional support staff, in order to encourage engagement with the issues and inform further action internally;
- Identifying areas to refer for action at University, Faculty and/or departmental level, and/or amongst professional support staff;
- Seeking input to a formal University response to the external developments (with or without reference to a draft response);
- Determining the governance process for signing off a formal University response;
- Establishing how additional intelligence will be shared, evaluated and disseminated.



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Preparing papers for the University Ethics, Research and Development Committee

The University Reserach Committee (UERDC) is a senior University committee which considers a substantial amount of business. To enable it to function efficiently and effectively, staff members are encouraged to **read and observe all of the guidance below.**

When planning an item of business for the UERDC, you should have a clear understanding of why it needs to go to the Committee, bearing in mind UERDC's remit as set out in its terms of reference (see *NCU Governance structure and terms of references*)

New policies and initiatives, strategic approaches and any other business with significant implications for the research and development of high quality research training in all our subject areas must be formally approved by UERDC; this is because they must be in compliance with the Quality Assurance Frameworks (QAA). An agenda item is therefore likely to be asking the Committee to do one or more of the following:

- Formally approve a policy/procedure
- Approve some recommendations for action with an implementation schedule where relevant
- Make a decision in relation to a number of options
- Express a view in relation to a particular issue/ proposed policy or recommendations, in order to inform a decision to be made by a third party (e.g., research group)
- Endorse a strategic need for further work to be carried out in a particular area, prior to bringing forward more detailed proposals.

Alternatively, you may report information for the Committee to note as part of its knowledge base – but you need to be clear why it needs to be brought to the Committee's attention.

However, the UERDC is not an appropriate forum for broad academic consultation: its role is to consider finalised proposals once such processes have taken place. Furthermore, UERDC does not have any direct



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funding control. However, you may wish in some cases to ask UERDC to endorse a proposed plan of action in order to strengthen the case for funding approval. Information relating to these factors will still have a bearing on the decisions UERDC makes in terms of feasibility, and should be included at an appropriate level of detail.

Writing papers

Papers submitted to the committee are documents that outlines proposals different subjects; as a starting point, you should be clear about the **purpose** of the paper. Is it:

- (a) to provide information?
- (b) to make a report on a completed course of action?
- (c) to make recommendations on policy or a course of action?
- (d) to put forward ideas and proposals in preparation for discussion?

Secondly, bear in mind for whom the paper is intended as this should help you to decide on the tone, content and level of detail required.

The first thing that needs thinking through is to be clear about what you are asking the Committee to do with your paper. General, unfocused discussion is not an efficient or productive use of Committee time, hence the convention is to highlight your instruction to the Committee as a freestanding sentence or paragraph in bold, e.g. **UERDC** is asked to approve this proposal. The instruction(s) should also be pulled out in the cover sheet to the paper (see below the Formatting Requirements section), so that members can see at a glance what they are being asked to do. This is particularly important if there are a number of instructions to the Committee distributed through the main paper.

The UERDC assessment is about whether you have a thorough grasp of the subject of your paper. You should be providing advice and guidance on the issues at stake, not vice versa. If you wish for action to be taken or decisions to be made, lay out specific options. If you are looking for a steer on a certain issue, make the parameters for discussion relatively narrow, and explicit. Remember that discussion time for your paper will be limited: the average slot for an item is around 10 minutes.



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You should briefly set out the background/context to your proposals. If the development of your item of business has involved consultation with the wider academic and/or professional support community, a summary of the process should be included in your paper so that the Committee can be confident that input has been sought at an appropriate level from representatives of the staff which the initiative is going to affect.

Although it is important to include sufficient detail to inform meaningful discussion, papers should be as concise as possible, focusing on the key information and summarising where appropriate. Specifically:

- 1. The Committee's focus is on strategic decision-making and points of principle. Operational detail is the responsibility of the University's professional support services, and should be kept to a minimum for UERDC's purposes.
- 2. You should not ask Committee members to process unmediated data for themselves: they rely on you to produce summaries and pull out key points.
- 3. Where detailed information is needed for context, this can be provided in the form of an appendix to the main paper, or via a link to further information online. Bulky appendices should be avoided.

Formatting requirements

With the exception of subcommittee minutes, all papers must be accompanied by a one side coversheet, which includes:

- 1. A brief indication of the paper's contents and its provenance
- 2. What the Committee is being asked to do with the paper
- 3. Where the paper contains information that is confidential, commercially sensitive, or might otherwise attract exemption under Freedom of Information legislation, the relevant FoI exemption and/or any security classifications must be noted.





In line with University branding and accessibility guidelines, UERDC papers should be presented in **Time New Roman font, point 12 minimum**. This includes the font on diagrams and/or tables.

To aid UERDC's discussions, **please ensure that pages are numbered** and that bullet points can be individually referenced i.e. (a), (b), (c) or (i), (ii), (iii), etc. For lengthy discursive papers, it is also helpful to number paragraphs.

In order to keep printing costs to a minimum, contributors are asked to present papers in **black and white** unless colour is absolutely necessary (e.g. for the presentation of line graphs or complex data where grayscale variants are not appropriate).

Please submit your paper in an editable format e.g. Word/Excel (Not PDF), so that the relevant agenda and enclosure numbers can be added for the Committee's reference. It is helpful to incorporate a document header for this purpose as part of your paper so that the original pagination stays intact once the above information has been inserted. (Note: the same principle applies to inserting page numbers).

Further University guidance on writing committee papers can be found in the document *Guidance on drafting and presentation of reports*. Examples of well-constructed papers are also available from the UERDC Chair on request.

What happens during the meeting

It is likely that you will be asked to attend Research Committee at an appropriate point in the meeting to speak to your agenda item. The Secretary will be in touch with details and to arrange a time. Please be prepared to present your paper formally as well as answering questions in the course of discussion. You are not expected to talk through the detail of the paper: assume that the members have read the paper in advance of the meeting. However, it is useful to focus the discussion by briefly pulling out key points and reiterating what the Committee is being asked to do. Please note that the average slot for an item is around 10





minutes.

Once the minutes of the meeting have been signed off by the Chair, the Secretary will send you a copy of the relevant minute for information. *You are expected to keep this for reference as part of your own records*.

Further action, including any wider communication of the outcome which might be required, and/or implementation of what the Committee has agreed, is your responsibility as project lead. For information on appropriate routes for dissemination/implementation, see the section 'Guidance on routes for consultation, engagement, dissemination, and implementation' within this document.

Developing research proposals

All research grant applications must go through internal authorisation prior to submission. However, it is strongly recommended that colleagues developing business other than routine reports for consideration by UERDC should consult with the wider academic community as part of the development process, **prior to submission to UERDC.** The same applies to initiatives that may have implications for other colleagues within the institution (e.g., administrative staff, student services, etc.).

You will need to plan your piece of work to build in sufficient time to consult with your chosen groups (bearing in mind their own deadlines for formal agenda papers) and respond to their input, prior to preparing your paper in time for the UERDC deadlines (see the Deadlines section in this document). The document *academic calendar* includes an annual timeframe of meetings for key research groups.

The Chair of UERDC should also be apprised at an early stage of any pieces of work which are under way, and should have sight of a final draft of the relevant papers before they are submitted to UERDC. In relation to the latter, you should be aware that the UERDC Chair's diary is very busy; therefore you should allow **at least a week** for comments on a paper (more if major revisions might be required).





The approval stages are as follows

- The applicant checks the resources and budget are correct and attaches the application form and any supporting documentation. He/she then completes a number of questions and submits the application to the Committee. Note that applicants should have already completed internal peer review and consulted their Head of Department about any resource implications of the application/tender before completing this stage.
 - → Find out in the *how to calculate your budget Research*Proposals document
- The committee checks that the detail of the application against the costing to
 ensure that staff salaries, estates and indirect costs, and terms and conditions
 of funding are acceptable to NCIUL and the application conforms to the
 funder's rules.
- The Executive Dean must be informed of the extent of research in which
 academic and research staff are engaged. He/she approves that the research
 can be undertaken within the School, direct costs have been included or can be
 met by the School, and that staffing implications, including requests for 'buy
 out' time are acceptable.
- The **Director of Finance** gives NCIUL approval that the application can be submitted to the external funder.
- The application can only be **submitted once** the above stages have been completed.



How to apply: internal approval

The chair of the Ethics, Research and Development Committee is the first point of contact for

discussions around preparing and submitting a research grant.

A template is provided as guideline for the writing up of a research proposal (see Writing a

Research Proposal).

Furthermore, a number of funders provide advice and guidance on how to write a good

proposal or what they expect from a justification of resources:

hiips://epsrc.ukri.org/funding/applicationprocess/preparing/writing/

hiips://esrc.ukri.org/funding/guidance-for-applicants/how-to-write-a-good-research-grant-

proposal/

hiips://www.leverhulme.ac.uk/funding/advice-choosing-referee

A range of electronic submission systems are used by awarding authorities as portals to

provide information about and submit funding proposals. The following are the most

commonly-used systems. However, the financial provisions of any research application or

contract with external sponsors must be scrutinised by the Ethics, Research and

Development Committee and approved by a Head of Department before they leave the

university.

European Commission

All projects are submitted and managed through the Research Participant Portal

hiips://ec.europa.eu/research/participants/portal/desktop/en/home.html

If you intend to submit an application or have any questions about how to manage your

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project please contact the EU team.

Royal Society

Royal Society grants are applied for online via the e-GAP2 system. This is a revision of the Society's former e-GAP system.

In order to access to the e-GAP2 you need to register with a password. Once registered you can create and submit your proposal online. The proposal will then be reviewed by the Research Support Office. If approved, the RSO will submit the proposal to the funder.

hiips://royalsociety.org/grants-schemes-awards/grants/applications/

When to apply

Most grant-giving bodies have specified closing dates for applications which are listed in their information guidelines.

A great deal of work has to be done both within the university and in the grant-giving organisations to process research grant applications and contracts so it is essential for proposals to be presented in good time.

Bear in mind that when planning your application the Research Committee needs at least nine working days' notice of your proposal, so that we have adequate time to assist you with the application and complete institutional approval before it can be submitted to the relevant funder.

Ethical Approval for research proposals



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Foreword

All members of the department - both staff and students - are expected to observe the code of conduct and ethical principles laid down by the NCIUL in their Code of conduct, ethical principles and guidelines. They should ensure that everyone for whom they are responsible in the department, and to whom the code and principles apply, observes them.

The University exists to advance and disseminate knowledge and learning while maintaining proper ethical standards.

The ethics Code of Practice

The purpose of this Code is to establish an ethical framework for the conduct of academic activity under the auspices of the University. It articulates a set of principles and standards to help identify and address ethical considerations, and sets out the procedures for conducting ethical review on behalf of the institution wherever such considerations have been identified, including formal approval where necessary.

1.3. This Code applies to all academic activity undertaken in the University's name or on its behalf, including research, teaching, consultancy and outreach work. This includes collaborative work even where the University is not the lead collaborator. It applies to all staff, students, visiting or emeritus staff, associates, honorary or clinical contract holders, contractors and consultants, across all subject disciplines and fields of study. All those involved in carrying out the activity are responsible for adhering to the principles outlined in this Code and abiding by the outcome of ethical review. Those undertaking academic activity on University premises using its facilities but not in the University's name are expected to abide by the standards outlined in this Code of Practice, although formal ethical review and approval might be carried out via other routes as appropriate.

Ethical principles and standards

The ethical framework sits alongside the need to comply with statutory and regulatory requirements, and with the requirements and standards of practice set out in guidelines published by scientific societies, funding agencies and other relevant professional bodies. The framework consists of principles and standards as opposed to rules, against which each case should be considered on its own merits. The key principle underpinning the ethical standards which apply to academic activities is that of avoidance of harm. This principle spans a broad range of considerations, including:



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- The welfare and interests of human participants (whether participating actively or through observation)
- The welfare and interests of those carrying out the activity
- Animals
- Cultural heritage
- The natural environment
- The reputation of the department, the University and academia as a whole
- The welfare and interests of the wider community.

Activities should neither include practices which directly impose a risk of serious harm nor be indirectly dependent upon such practices.

For research or further activity drawing on research involving humans (including participation, observation and/or data), the default position is that **informed written consent** is required from those involved and/or their representatives. If researchers wish to deviate from this norm, they should make a case for doing so in line with the core principles of this ethical framework and in accordance with data protection legislation, for consideration as part of the formal ethical review procedure. Consent should be granted voluntarily. Where research involves vulnerable groups (e.g. children, prisoners, those suffering mental or physical illness), particular care should be taken to safeguard their welfare and interests; and additional safeguards such as Disclosure and Barring Service (formerly CRB) checks should be implemented as appropriate. In line with the University's Code of Practice on Research Integrity, participants and/or their representatives should be provided with details of a first point of contact through which any concerns can be raised: usually the Head of Department and/or the chair of the UERDC.

Researchers should plan in advance how potential incidental findings relating to the welfare of participants or third parties are to be handled, within the boundaries of the law, and incorporate this into the consent process.

Particular care must be taken with collecting, handling and storing sensitive, classified and/or personal data, in line with the **Data Protection Act** (1998) and subsequent **GDPR 2018**. But also with internal NCIUL policies for the treatment of data. Such data should be kept securely and protected from unauthorised access, and there should be a clear and documented access control process for granting and revoking access to the data. Particular care should be given to ensuring that human data cannot be linked back to individuals' details unless by authorised persons. It is essential that all sensitive, classified and/or personal data are disposed of appropriately, securely and auditably at the end of their lifespan, in line with legal and funder requirements.





At the end of the research project (unless consent has been obtained *in writing* from those individuals who were recruited) any personal information must be destroyed. The only scenario where researchers are exempt from doing so is to anonymised their data; this can allow researchers to retain their data, provided data will be stored without any possibility of identifying the individuals who took part in the study.

The confidentiality of information should be respected within the boundaries of the law. Where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities.

In considering the welfare of all those involved in a project, including the researchers themselves, individuals should be aware of and comply with the University's Health and Safety Policy, and any specific NCIUL policies and procedures relating to health and safety, as well as the basic legal requirements articulated in the Health and Safety at Work Act (1974). Where relevant, risk assessments should be carried out for those conducting or participating in a project or affected by its conduct, and in relation to any impact on the environment. Appropriate insurance should be put in place, in consultation with the University's Insurance Officer (via standard NCIUL procedures where these exist).

It is fundamental to academic freedom that the interests of funders and other stakeholders should not bias the design, conduct or findings of research. It is also a fundamental principle of academic research that researchers should be able to publish their results freely. Funders may wish to impose restrictive clauses that allow delays in publication, for example to allow protection of intellectual property to capture commercial value. Where such clauses do not infringe the fundamental freedom of the researcher to publish their findings, they can be accepted: the University will seek to include provisions for work to be published with the minimum delays consistent with these considerations. In other cases (e.g. contract research for industry), funders may wish to make publication dependent on their consent. The University would expect these decisions to be made reasonably and without undue delay, but with appropriate regard for openness, transparency and the Freedom of Information Act (2000).

The University does not bar academics from working with the defence sector. However, all research involving potential or actual defence and/or security applications should undergo ethical review, i.e. including 'dual use' research, defined as research that has military as well as civilian applications. Particular consideration will need to be given to weighing up the



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benefits against the risks of direct or indirect harm. It is especially important that appropriate measures should be put in place to ensure information security in order to avoid misuse.

Activities conducted overseas should take account of political, social and cultural sensitivities in their design and conduct. Regarding countries/regimes with a poor human rights record or identified as dangerous by the Foreign & Commonwealth Office, particular care must be exercised in relation to the welfare and interests of all those involved, both the participants and those carrying out the activity. With respect to countries with emerging economies, the activity should involve reasonable use of local resources, and benefit to the local community should be ensured. Activities conducted overseas should comply with the statutory and regulatory requirements of the country/countries in question, as well as those which apply to the UK. In planning activities, individuals should take account of the ethical standards and processes of the country/countries in question as well as those of the University.

2.14. The quality and robustness of a research proposal may carry ethical implications in that any shortfall undermines the investment made by participants, funders and other stakeholders, and harms the reputation of the department, the University and academia as a whole. The primary mechanism for assuring the quality of research proposals is **departmental peer review**; however, where proposals have been referred for ethical review in response to other elements of the University's ethical framework, concerns relating to quality and robustness can legitimately be raised as an ethical issue.

Particular care needs to be taken with regard to research and other academic activities related to political extremism and terrorism. Any such activities must be reviewed by Ethics, Research and Development Committee; in addition, where necessary, advice should be sought from the University's Prevent Lead (the Registrar & Secretary).

Ethical management

All academic activities which have an ethical dimension should undergo formal ethical review and signoff. The cornerstones for the management of ethical issues in the University are self-reflection, explicit discussion, institutional accountability, and proportionality. That is to say, individuals should take responsibility for actively considering whether their activities fall within the scope of the University's ethical framework, and where this is the case, the activities should be formally considered and signed off through the University's governance structures as outlined below, with regard to the degree and risk (including the impact and/or likelihood) of potential harm. The purpose of ethical review is not to deter challenging activities, but to enable it to take place on a sound ethical footing and ensure that the University can defend the work carried out in its name and on its premises, and those





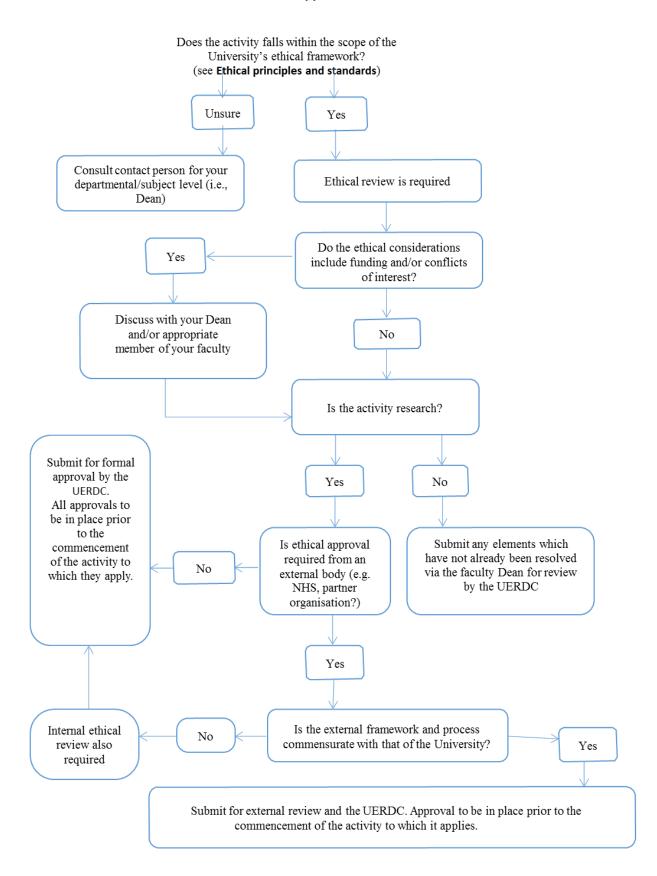
involved, should the need arise.

All research undertaken in the University's name or on its behalf, regardless of funding source, which falls within the scope of the University's ethical framework should be submitted for review and formal approval via the ethics governance structures outlined below (see also diagram below). Ethical approval should be in place prior to the commencement of the activity to which it applies. Retrospective ethical approval is fundamentally unethical and is not permitted.





Procedure for ethical approval





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The majority of academic activities which have an ethical dimension will undergo formal ethical review via the University's internal ethics governance structures.

However, in some instances, research will require ethical approval by an outside body (e.g. the NHS or a partner organisation). For staff-led research, where the external ethical framework and process is commensurate with that of the University in terms of scope and rigour (e.g. the NHS or a research intensive UK HEI), internal ethical review is not a University requirement. However, the Ethics, Research and Development Committee may recommend an additional internal review if deemed appropriate according to the scale of risk. To this end, where the University is relying upon an external process to carry out due ethical scrutiny, the NCIUL project lead should ensure that the Ethics, Research and Development Committee is informed of the proposed activity in a timely fashion. In all instances, the final outcome of external ethical scrutiny should be reported by the NCIUL project lead to the UERDC committee for its records. Clear and accessible supporting records for the ethical approval should be maintained by the NCIUL project lead.

Where the external ethical framework and process concerned is not commensurate with that of the University, the matter should in addition be referred for review via the University's internal ethics governance structures. Where a judgement is required regarding the parity of an external ethical framework and review process, this should be made in consultation with the chair of the relevant department/subject-level ethics subcommittee.

Where research projects transfer part-way into the University owing to staffing changes and fall within the scope of the University's ethical framework, the NCIUL lead should inform the Chair of the UERDC committee of the ethical scrutiny which the project has undergone, and the UERDC committee Chair should decide with reference to the above principles whether further scrutiny on behalf of the University is necessary.

The fundamental responsibility for identifying ethical considerations and referring them for review lies with the individual initiating and/or leading the activity. The University Senate has agreed that it is important not to take such responsibility from individuals who need to be proactively engaged with any potential ethical issues in their own work. Where an activity is initiated by a student and falls within his/her programme of study, this responsibility is shared between the student and the member of staff overseeing the activity. These individuals should consider whether their activity falls within the scope of the University's ethical framework, and refer it for ethical review if so, prior to commencement. As far as possible, ethical considerations should be identified and addressed within the proposals submitted for review. A checklist is provided as Appendix A to this Code, indicating where ethical considerations are likely to arise. Where in doubt or in need of further advice, researchers should seek guidance from the Ethics, Research and Development Committee in the first instance, referring on to the Chair of the University UERDC Committee and/or the Registrar. Ethical





considerations should be kept in mind throughout the lifetime of the activity and if circumstances change (e.g. significant amendments to the approved protocol for a project), additional ethical review/approval should be sought as necessary from the body/bodies which originally considered the proposal. Where this involves a body external to the University Ethics, Research and Development Committee should be notified and records maintained.

It is important that the University is aware of all projects with ethical implications being undertaken under its auspices. The Ethics, Research and Development Committee should therefore maintain clear, regular and proportionate lines of communication with the relevant departmental research groups regarding the outcomes of its research-related business. This is particularly important in the case of subject-level ethics committees that undertake ethical review for more than one department. Departmental academic staff members also play a role in supporting the identification of ethical considerations and referral for ethical review through procedures for planning and reviewing research such as peer review.

The University operates a devolved structure for conducting ethical review and approval. During approval a lay member should be present to provide additional assurance in respect of objective oversight and unbiased scrutiny. The lay member must not be an academic and should have no affiliation to the University.

The UERDC committee may agree to undertake expedited reviews where, for example, the ethical considerations relating to the activity carry only a minimal risk or the work has similarity to projects previously approved (i.e., routine approval).

Further guidance on routes of referral in the flowchart of the process (see above).

The University is responsible for providing support for those in key leadership roles within the governance structure for ethics, including committee members, ensuring that they have access to the necessary knowledge and skills training in order to perform their role effectively. It should also take the lead on bringing this policy to the attention of all those to whom it applies (e.g. through central induction provision), and ensure there are adequate provisions made for training and development to enable staff and students to understand what is expected of them.

Undergraduate projects - deadlines for ethics submissions

Most undergraduate projects are Routine, Routine ethics applications can be submitted at any time. For Non-Routine applications, there are three deadlines:



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These are:

Wednesday 1st November,

Wednesday 15th November and

absolute final deadline, Friday 1st December.

If you can submit by the first deadline (you have found a supervisor and agreed a topic), please do so. Remember the sooner you submit and get approval, the sooner you can start your project. The 1st December is a final deadline and any applications submitted after that will not be reviewed.

Ethics applications need to be marked as either Routine or Non-Routine:

Routine: If the researcher or supervisor decides that the proposed study is so close to a previous study that has been reviewed within the last 3 years or renewed (for a maximum of 2 additional years) by the Ethics, Research and Development Committee, then you may proceed with your routine research once you have completed and submitted a routine application. When submitting a routine application, the approval number from the original (non-routine) application must be included on your application form. You must also provide copies of all original documentation with your routine ethics application form, including all appendices (and final versions of forms if amendments were required). If you cannot provide the original documentation or ethical approval has expired and cannot be renewed, you will be need to complete a new non-routine form.

Non-Routine: If the proposed study raises ethical issues for which the researcher / supervisor has not had previous approval, then the application is Non-Routine and must be considered by the ethics committee. The study cannot proceed until the researcher has received a numbered ethical approval certificate.

Please note therefore it is the researcher's responsibility (or the supervisor if the researcher is a student) to decide whether the proposed study can be considered Routine or Non-Routine. Where there is any doubt about whether a proposal is routine then it should be categorised as



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non-routine.

Forms

There are three different ethics application forms. Make sure you complete the right one. Students should consult their supervisor before completing the form.

- 1. Research with adults: Adults Form
- 2. Research with minors (under 16 years): Minors Form
- 3. Research using secondary data: Secondary data form

Attach any relevant documentation. Sign the form and, if you are a student, your supervisor must also sign it. Please submit your application electronically to ethics@nciul.co.uk

Routine applications can be submitted at anytime.

How to apply for renewal of ethics approval

Ethical approval is given to non-routine projects for a period of 3 years. To obtain an extension for a further 2 years, please complete the below application, confirming that no details of your research have changed. Renewal applications need to be submitted electronically to ethics@nciul.co.uk along with a copy of all original documentation pertaining to the associated non-routine application i.e. application forms, appendices, etc. If you are unable to provide original documentation or the Committee confirms that ethical approval cannot be renewed, you may be required to complete a new non-routine form for your study.

Undergraduate students and involvement in clinical projects

Undergraduates are not allowed to undergo clinical project. By clinical, we mean projects which would require getting NHS ethics approval (now referred to as COREC) for research on patients or NHS staff. Procedures for gaining COREC approval have become much more onerous, time-consuming and



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complex in recent years, and the effort required for such approval means it is not appropriate for undergraduate projects. The only exception to this will be if an undergraduate, through their existing employed work, is already doing research on a project which has received COREC approval for the work that individual is doing- i.e. no new COREC application would be required.

Note about NHS approvals:

If your application concerns clinical or patient groups or is similar to other studies that require National Research Ethics Service Approval (NRES), you must explain in your application why NRES permission is not required. You must also submit the NRES self-assessment check verifying this with your application. https://hra-decisiontools.org.uk/ethics/

Research involving minors (under 16 years of age)

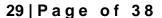
Sometimes students carry out research for their projects / dissertations in an ongoing study of their supervisors and which their supervisors have ethics approval for. In these cases, students still need to apply for ethical approval and their application is always non-routine. DBS/CRB checks: Anyone carrying out research with minors must undergo a CRB check. Please note that this can take up to three months to process so you should plan accordingly. The research cannot begin until the individual has been approved (see DBS section below). Please note that research involving minors is always non-routine.

DBS Checks

Staff DBS checks: Staff requiring a DBS check (formally known as CRB) will be able to apply for one through the College. Please contact the Finance department (insert email or contact details here)

Student DBS checks: Students requiring a DBS check (formally known as CRB) will be able to apply for one through the College. Please read the following information for instructions on how to do so:







- 1. Confirm with your supervisor that a DBS check is required.
- 2. Contact the finance department (insert email here) and provide your full name, student number, date of birth, course and email address. Please put DBS check in the subject header and copy your supervisor and ethics@nciul.co.uk into this email as proof that they have agreed to your check. If you do not copy in your supervisor, your email will not be processed.
- 3. The HR office will set up an application for you to complete. After you have done so email HR department (insert email here) to make an appointment to show the original supporting documents you selected to prove your identification when making the application. Please note that you must have a copy of the original documentation, as no photocopies or printouts will be accepted and if you do not have all the appropriate documentation the check cannot not be carried out.
- 4. The Disclosure result will generally be issued to you by post within 7-10 days of the check being completed.
- 5. NCIUL will not receive a copy of the DBS certificate. You will have to scan and email a copy to the HR department (insert email here). Alternatively, you may arrange to bring in the original certificate so that a copy may be taken.

Important: You must *not* begin your study until your DBS result has been seen and accepted, and your Ethics Approval Form has been approved. If you already have a DBS check that was not processed by NCIUL, we will not accept it. NCIUL does not participate in the DBS update service. You must therefore have another check processed through NCIUL. Please follow the steps above.

Useful links

- <u>UK Data Archive (UKDA)</u> guidance on data management and sharing
- Code of Human Research Ethics (BPS)
- Ethics Guidelines for Internet-mediated Research (BPS)



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• References:

- o Bersoff, D.N. (1995). Ethical conflicts in psychology
- o Kimmel, A.J. (1996). Ethical issues in behavioral research: a survey.
- Panter, A.T. and Sterba, S.K. (2011) Handbook of Ethics in Quantitative Methodology. London: Routledge

Information on how to request an amendment to existing studies

Rarely, you may need to slightly modify an ongoing project (e.g. change the format of a questionnaire that is causing confusion). If this represents a new experiment or study, this should be applied for using the Routine or Non-Routine form. However, if this is an alteration to an ongoing experiment or study, you can submit a request for amendment. You should detail your requested amendment (covering all aspects of the original form that are altered by your amendment, including data sharing/security) in a letter addressed to the Chair; you should attach new versions of consent forms/information sheets where relevant, and any new materials; you should also attach your original application form. Any original materials that have been modified should have new version numbers and dates, so that participants can be tracked. Your email should be entitled Modification to Study and your reference number. The UERDC committee will let you know whether your amendment is approved, requires alteration, or is rejected. This communication must be received before you can implement your proposed modification.

Deadlines

A table of UERDC deadlines for the current academic year is provided below.

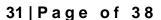
Deadlines for inclusion on the agenda

Please contact the Secretary at any point up to the deadline in question to propose items for a particular UERDC meeting. You will need to:

(a) specify the title of your paper(s), and



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(b) indicate what the Committee will be asked to do with the information i.e. consider/note for information/endorse/formally approve etc.

(c) specify whether your paper is FOI Exempt and/or confidential.

Following the deadline, the Secretary compiles a list of the agenda items proposed, for approval by the Chair. Unless you hear otherwise, you should assume that your item has been accepted.

Further items are only accepted after the deadline by agreement with the Chair. Please note that in line with University practice, the Committee does not accept tabled papers, except in exceptional circumstances by prior agreement with the Chair.

Deadline for submission of papers

Papers should be sent **complete and ready for circulation** to the UERDC Chair via email (ethics@nciul.co.uk) on the day specified.

The stated deadlines allow the UERDC to perform a basic check on the papers, then mark up, collate and print them prior to circulation a week in advance of the meeting. It is important that the papers go out promptly in order to allow members sufficient reading time.

Please note: missed deadlines, incorrectly formatted papers and/or incomplete submissions (including those requiring further adjustments or authorisations) cause significant disruption to the Committee's ability to function effectively. Your co-operation in submitting papers on time and ready for circulation is appreciated.





Date of meeting	Deadline for submission of papers	Deadline for inclusion on agenda
Day – month –year	Day – month –year	Day – month –year
e.g., Wednesday 20 June 2018	e.g., 12pm, Monday 11 June 2018	e.g., 12pm, Wednesday 30 May, 2018

Note: the earliest deadline would be Deadline for inclusion on agenda, mid-deadline be the Deadline for submission of papers, and latest be the Date of meeting (see example at the bottom of the table above). A date for inclusion on agenda and submission of papers may be included as well. If not otherwise specified, deadlines are intended by 6pm on the day of deadline.

IMPORTANT NOTE:

In exceptional circumstances it may be possible to send out papers which have already been accepted on to the agenda in a second, later circulation. This should be agreed with the Chair in advance of the official deadline for papers. However, this should not be seen as the 'fall back' option. UERDC has explicitly requested that second circulations should be as brief as possible since the members of the committees are not always able to engage with substantial amounts of information at short notice.



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Deadlines For Research Funding

DEADLINE	FUNDER	SCHEME
Pre-call	Economic & Social Research Council	Open Large Grants Competition
Pre-call	Economic & Social Research Council	Trust and Global Governance Large Grants
10 Apr 18	Open World Research Initiative (AHRC)	Creative Multilingualism
12 Apr 18	Economics & Social Research	JPI Urban Europe-NSFC call: Sustainable
12 11p1 10	Council	and liveable cities and urban areas
15 Apr 18	Royal Society	Pairing Scheme
16 Apr 18	Wellcome Trust	Research Enrichment Funding
17 Apr 10	Natural Environment Research	Open Knowledge Exchange (KE)
17 Apr 18	Council	<u>Fellowships</u>
18 Apr 18	Wellcome Trust	Collaborative Award in Science
18 Apr 18	Wellcome Trust	Sir Henry Wellcome Postdoctoral
18 Apr 18		<u>Fellowship</u>
		Research Grants, New Investigator, Stand
24 Apr 18	Biotechnology & Biological Research Council	Alone LINK, Industrial Partnership
		Awards, BBSRC/Brazil joint funding
		Research
25 Apr 18	Medical Research Council	Senior-Non-Clinical Fellowship
25 Apr 18	Medical Research Council	Career Development Award
26 Apr 18	Arts & Humanities Research Council	Development through the Creative Economy in China



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20 1 10	Natural Environment Research	Global Partnerships Seedcorn Fund
30 Apr 18	Council	<u>2018</u>
1 May 18	Academy of Medical Science	<u>Springboard</u>
2 May 18	Medical Research Council –	Research Grants, New Investigator
	Molecular & Cellular	Research grants
2 May 18	Royal Society	Wolfson fellowship
3 May 18	Economic & Social Research Council	Governance after Brexit programme – Small Grants
3 May 18	Royal Society	International Collaboration
9 May 18	Biotechnology & Biological Sciences Research Council	David Phillips Fellowships
10 May 18	Leverhulme Trust	Visiting Professorship
10 May 18	Leverhulme Trust	Major Research Fellowship
15 May 18	Economic & Social Research Council	Climate change centre
15 May 18	London Mathematical Society	Research in Pairs
16 May 18	Medical Research Council – Infection	Research Grants, New Investigator
10 May 16	& Immunity	Research grants
17 May 18	Leverhulme Trust	Philip Leverhulme Prize
21 May 18	Natural Environment Research Council	Impact Award
22 May 18	Economic & Social Research Council	Governance after Brexit programme –
22 May 18		Large Grants
23 May 18	Medical Research Council –	Research Grants, New Investigator
23 Way 10	Populations & Systems	Research grants
30 May 18	Medical Research Council –	Research Grants, New Investigator
	Neuroscience & Mental Health	Research grants
31 May 18	Arts & Humanities Research Council	Early Career Researchers, Highlight notice, leadership Fellowships
5 Jun 18	Economic & Social Research Council	Climate change network plus





14 Jun 18	Economic & Social Research Council	Transnational organised crime: Deepening and broadening our understanding
	Research Council UK & Social,	
18 Jun 18	Behavioral & Economic Sciences	Expiry date of Memorandum of
	Directorate, US National Science	<u>Understanding</u> between UK and US
	Foundation. RCUK-SBE	
1 Jul 18	Waterloo Foundation	Child Development
4 Jul 18	Wellcome Trust	Investigator Award in Humanities and
		Social Science
4 Jul 18	Wellcome Trust	Collaborative Awards in Humanities and
		Social Science
5 Jul 18	Wellcome Trust	Seed Awards, Science
6 Jul 18	Wellcome Trust	Research Fellowships in Humanities and
		Social Science
6 Jul 18	Wellcome Trust	University Awards in Humanities and
		Social Science
9 Jul 18	Wellcome Trust	Research Enrichment Funding
17 Jul 18	Natural Environment Research Council	Standard Grants

Deadlines for submission of ethics approvals

There are submission deadlines for Non-Routine applications to the ethics committee. Applications should be submitted in the days leading up to this date. Submissions after this date will not be considered until the following deadline. In most cases, applicants will receive a response within 3 weeks of the submission deadline:



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2018: 12 January, 16 February, 16 March, 13 April, 18 May, 15 June

Please submit all applications electronically to ethics@nciul.co.uk





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Date of next review:	04/2019	
Related documents:	 Guidance on drafting and presentation of reports How to calculate your budget – Research Proposals Templates Minutes of the research committee Presentation of report Committee Agenda Writing a Research Proposal Forms for ethics approvals 	
Approved by:	Research and Development Committee, XXXXXX	
Equality impact Assessment undertaken:	n/a	
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V 1.0	Draft version	
V 1. <mark>x</mark>	Version amended in accordance with OU recommendations and other members of the committee Minor formatting changes	



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