Guidance Notes for the Implementation of the University Research Ethics Policy and Code of Practice

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<th>Author(s)</th>
<th>Jo Hutchinson</th>
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1. **Introduction**

As a reflection of University of Derby core values, the University is concerned to protect the rights, dignity, safety and privacy of research participants, the welfare of animals and the integrity of the environment. The University is also concerned to protect the health, safety and academic freedom of researchers and the reputation of the University as a centre for appropriately conducted, high quality research. Underpinning the policy are the ethical imperatives of ‘Do No Harm’ (non-malfeasance) and ‘Do Good’ (beneficence). There is also a need for the University to comply with legislation and the requirements of external organisations (e.g. professional bodies and research councils). The University Research Committee (URC) is responsible for the development and implementation of the University's Research Ethics Policy and Code of Practice which has been approved by Academic Board.

The University also needs to ensure that research activity within the University is monitored to ensure that it is ethically appropriate and approved. Specifically:

1. All staff research, both funded and non-funded.
2. Research activity associated with taught undergraduate programmes [UG], normally as part of Independent Studies.
3. Research activity associated with postgraduate taught [PGT], postgraduate research (PGR) and postgraduate professional (PGP) students

Within this note the term ‘research’ or ‘research project’ is used to include an independent study, project, major project, and applied research project.

These guidelines should be considered alongside other guidance notes and policy documents including the University of Derby Research Ethics Policy and Code of Practice, and the Research Governance Infrastructure document.

2. **Implementation structure**

The primary responsibility for the ethical consideration and approval of research rests with College Research Ethics Committees (CRECs). It will be these Committees’ responsibility to monitor the ethical status and if appropriate give ethical approval for applications within their academic areas.

If a CREC does not feel it is able to come to a conclusion about a specific project or if significant concerns are identified which cannot be resolved at CREC level for post-graduate and staff requests, it can seek advice from their College Research Committee. On occasions where a conclusion cannot be reached within College structures the request for ethical approval can be brought to URC. It will not be regarded as appropriate to pass applications associated with UG students onto a CRC; if a CREC has difficulty approving such an application.
it should be refused. However, should such an application have ‘wider implications’ a CREC should make the University Lead for Research Integrity aware at the time and record it through annual monitoring.

Research Ethics advice and guidance will be available to CRECs from URC and Research, Innovation and Academic Enterprise. Much of this will be via the developing Research Ethics and Integrity web site (http://derby.ac.uk/research/uod/ethics/) which includes guidance in use on issues such as data collection in languages other than English, and on-line research.

Requests for ethical approval for studies undertaken by UDOL students will be considered by a UDOL Research Ethics Committee. Where concerns arise that require further consultation these can be passed to the relevant CREC for their consideration. Any appeals would be taken via the University Lead for Research Integrity to URC.

3. Annual monitoring

As part of the University’s annual monitoring cycle an annual report will be compiled by URC based on systematic feedback from each CREC. This is an opportunity for committees to disseminate good practice, highlight concerns which may require support at a University level and identify staff development needs.

4. Ethical approval documentation

URC has developed two standardised application forms for students on taught programmes, and staff and post-graduate research students. CRECs may amend the forms to make them more appropriate for their needs, but will need to secure approval for any amendments from URC prior to its implementation.

5. College Research Ethics Committees

Each college normally has one College Research Ethics Committee (CREC). In exceptional cases a college may need more than one CREC to serve the best interests of their researchers and students. Their purpose is to ensure that research is conducted according to appropriate ethical, legal and professional frameworks, obligations and standards. Specifically their role is to implement the University of Derby Research Ethics Policy and Code of Practice and associated guidelines and procedures. This relates to research activities undertaken by all staff, and students pursuing undergraduate (UG), postgraduate taught (PGT), postgraduate research (PGR) awards or by a visiting researcher.

CRECs will report to their College Research Committee (who will receive a summary report of their meetings), who in turn report to the University Research Committee.
Detailed guidance on process and procedures for CRECs are developed and maintained by URC. These are held on a central intranet site. The Universities’ Research Governance Infrastructure document details the decision making powers, meeting schedule and composition requirements for CRECs.

6. **CREC Chairs Action**

It is recognised that, for example, for staff seeking approval for research projects related to applications for external funding and PGR students it may not be possible to delay consideration of a project until the next meeting of a CREC. Therefore a College must establish the option for consideration of applications by committees outside normal meetings via e-mail. The Chair and two other academics (at least one of whom should be a CREC member) must review an application presented in this way. Responses should be via a pro-forma document in order to ensure consistency. If the Chair does not feel that they can come to a decision about an application made in this way they may:

1. Ask for resubmission of the application after significant revisions.
2. Ask for clearly defined revisions which if appropriately met can be approved by ‘Chair’s Action’
3. An extra-ordinary meeting of the specific CREC can be convened which could include requesting an external advisor to attend
4. Delay approval while advice is sought from a full meeting of the CRC. This could lead to the application being passed on to URC for final decision.

However, consideration of applications outside the fixed committee meetings must not be used as an excuse for colleagues’ bad planning.

CRECs will be required to respond to applications within 6 weeks with a target period of 4 weeks. Under specific circumstances, for example, for research being undertaken as part of a funded contract the CREC will be expected to expedite the decision.

7. **Approval process for students on taught research programmes**

It is recognised that for large programmes or programme clusters it will not be logistically possible for a CREC to consider every undergraduate research ethics application individually. Hence the following approach is advised.

- The generic ‘students on taught programmes request for ethical approval’ form should be used unless a CREC has agreed alternative special provision with URC.
The student will generate their ethical approval form alongside their research proposal which will be reviewed and considered by a member of academic staff (usually their research supervisor). They have authority to approve ethics applications.

All applications for taught post-graduate students will be assessed by two academic members of staff, one of whom should be on the CREC committee. If there are a large number of students on programme it is not necessary for all applications to be seen by the full committee and the sampling procedure can be invoked.

Under particular circumstances (e.g. requirements of a professional body) there may be a need for all taught post-graduate student applications to be scrutinised by a CREC.

Applications for ethical approval that are considered to be more than minimal risk will be discussed by the member of academic staff with the appropriate Independent Studies co-ordinator (or equivalent). If they reach agreement the research supervisor will take this forward. If they do not, the ethics application should be reviewed by the CREC.

It will not be regarded as appropriate to pass applications associated with UG students onto URC; if a CREC has difficulty approving such an application it should be refused and the student advised accordingly.

It will be the responsibility of the student to ensure that any conditions attached to approvals are met and agreed with their research supervisor before research commences.

It will be the responsibility of the research supervisor to report to their Independent Studies co-ordinator (or equivalent) and the CREC that conditions were met before research commenced.

The CREC should review any full applications which the Independent Studies co-ordinator has identified as needing their consideration - i.e. those that have not been signed off by the Independent Studies co-ordinator.

If it is a requirement by an external agency, such as a professional body, a College Research Ethics Committee may need to consider all under-graduate applications.

The Chair of a CREC may choose to divide a large number of ethical approval applications between Committee members for consideration prior to the meeting. The individual members will then provide feedback to the whole Committee during the meeting, raising any issues or concerns that have been identified.

To ensure that each CREC is able to monitor the ethical status of requests throughout their areas of responsibility all applications should be made available on request by the CREC. The Chair of the CREC should select a sample for review at the meeting. This would normally be between a maximum of 15% and a minimum of 10 applications. The sample could include applications from each research supervisor/tutor. The process of reviewing a sample is to assure quality and consistency, not to approve or reject applications.
If CRECs consider there to be inconsistent or poor practice in terms of advice being provided to students these should be raised through organisational monitoring procedures which in the case of undergraduates would go firstly through College Quality Enhancement Committees (CQEC) and the University Quality Enhancement Committee (UQEC).

To allow members of CRECs to appropriately consider proposal forms they should be submitted in advance to a deadline defined by individual committees.

It should be noted that the purpose of any CREC is to consider only the ethical issues related to applications made. It is not the role of the Committee to comment upon other aspects of a research project, for example the methodology or literature review, or to offer guidance on these aspects, unless these have ethical implications. In addition, no applicant whose ethical research proposal is being considered should benefit in any material way from the Committee's deliberations through feedback provided on such aspects. The potential success or otherwise of a research project should not be positively affected by feedback provided in any respect other than ethical issues.

Undergraduate students may be informed of the outcome of their ethical approval applications by e-mail via their supervisor. Appeal would follow normal academic procedures.

8. Approval process for staff and post-graduate research students
The following provisions apply for all academic staff and post-graduate research students including those studying via professional doctorate routes.

- The generic ‘PGR and staff on taught programmes request for ethical approval’ form should be used unless a CREC has agreed alternative special provision with URC.

- All applications for post-graduate research students will have been scrutinised by an academic member of staff (normally the research supervisor) to ensure that the form is appropriate for submission.

- All applications for staff, post-graduate research and post-graduate professional should be reviewed by the CREC.

- The Chair of a CREC may choose to divide a large number of ethical approval applications between Committee members for consideration prior to the meeting. The individual members will then provide feedback to the whole Committee during the meeting, raising any issues or concerns that have been identified.

If CRECs consider there to be inconsistent or poor practice in terms of advice being provided to students or colleagues these should be raised through organisational monitoring
procedures, being the College Quality Enhancement Committees (CQEC), and the University Quality Enhancement Committee (UQEC).

If a CREC does not feel it can approve an application it can either:

- Deny approval outright
- Ask for resubmission after significant revisions
- Ask for clearly defined revisions which if appropriately met can be approved by 'Chair's Action'
- Delay approval while advice is sought from CRC/URC

To allow members of CRECs to appropriately consider proposal forms they should be submitted in advance to a deadline defined by individual committees.

Staff or post-graduate research students may appeal a decision following the usual academic procedures.

A member of a CREC whose application is being considered will be asked to abstain from the discussion, and may be asked to leave the room whilst consideration of the application takes place. The Chair of the Committee may not approve his/her own ethical approval application, and should pass the Chair of the Committee onto another member of the Committee while his/her application is being considered. Likewise, the Chair must abstain from consideration of the project and may be asked to leave the room if requested by other Committee members.

It should be noted that the purpose of any CREC is to consider only the ethical issues related to applications made. It is not the role of the Committee to comment upon other aspects of a research project, for example the methodology or literature review, or to offer guidance on these aspects, unless these have ethical implications.

Committees may request that applicants submit several ethical approval applications at different points throughout their research, and charge the supervisor with supporting this process. A request of this nature should be included in the feedback provided to the applicant.

All Postgraduate students and staff members should be formally told of the result of their ethical applications either by email or letter. These can be signed by any Committee member, however they should be signed on behalf of the Committee and its Chair, rather than one member of the Committee, as the decision to approve/refer/refuse is one made collectively and as such the letter needs to reflect this process.
9. Consent
Some projects will require a participant informed consent form to be produced. Applicants should prepare their own for use in their particular projects. Applications requiring this document should not be approved without evidence of the participant consent form being provided and this should not be omitted from the process when it is required. In addition, participants should be clearly informed of the procedure to be followed should they wish to withdraw from a research project at any time. Should participants be anonymous, a reference number should be provided by the researcher and allocated to participants along with a clear withdrawal process.

10. Storage of requests for ethical approval
Only ethical approval forms for PGR students are filed in the Research Office. All other forms are stored electronically on an appropriate College shared drive with restricted access to a CREC folder. Members of each CREC should be able to access their own restricted area. Some subject areas choose to store final versions of approved applications on Turnitin. Paper copies of ethical approval forms from all other applicants may be retained by supervisors or returned to applicants. However, every ethical approval application made by any student/staff member is to be stored on the shared drive in accordance with the University of Derby Records Retention Policy.

11. Sensitive Research Material
The University has developed a guidance note on handling sensitive research materials. This guidance is for researchers whose research involves a need to see, acquire or store material that could be viewed as illegal or that may be of interest to police, security or intelligence services.

12. Data Storage
The University has a ‘Records Retention Policy’ (dated March 2014) which provides some advice on the length of time that documents should be stored. The advice is not fixed in terms of retention of primary data, laboratory notes and consent forms. However, prevailing practice suggests that students should be advised to store data securely for a minimum of six years. This could be extended to 10 years for post-graduate research students who may not publish their work straight away.

The University has a Data Code of Conduct that should be followed with regard to secure data storage and transmission.
13. **Risk**

Some research projects will require the inclusion of a risk assessment where there is identifiable material or psychological risk to the researcher(s) or participant(s). The British Psychological Society (BPS) suggests, however, that the consideration of risk may also be required in other areas, for example when working with vulnerable participants or when using employee data. Whilst the BPS acknowledges that such risks are not always easily identifiable, it recommends the identification and assessment of possible risks be included in the research project design and considered through the ethical approval process. CRECs should note this advice and ensure that such considerations are made as part of the approval process where appropriate in their subject areas.

Some research projects will require the inclusion of a health and safety risk assessment to ensure that risks have been assessed and procedures established for laboratory and fieldwork. Advice can be found on the Health, Safety and Wellbeing pages of the intranet: [https://staff.derby.ac.uk/sites/hr/Health-Safety/Organisational-Safety/Pages/A-Z.aspx](https://staff.derby.ac.uk/sites/hr/Health-Safety/Organisational-Safety/Pages/A-Z.aspx). Whilst CRECs need to be assured that a risk assessment is in place, it is not their role to check or review the assessment itself.

14. **Research carried out under the auspices of the NHS**

Staff and student researchers need to ascertain if review by an NHS REC is required for their proposed projects as set out in section 2.3 of the harmonised UK-wide edition of the Governance Arrangements for Research Ethics Committees (GAfREC), published by the UK Health Departments in May 2011 ([http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/](http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/)). In addition some legislation, such as the Clinical Trials Regulations, Human Tissue Act and Mental Capacity Act specifies that research in these areas may require ethical approval from an appropriately recognised REC whether or not the research takes place within the NHS.

Guidance on whether research requires NHS ethical review under either the law or the policy of the UK Health Departments’ can be found on the HRA website at [http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/](http://www.hra.nhs.uk/resources/before-you-apply/is-nhs-rec-review-required/)

If your research involves undertaking research on the premises of a NHS/HSC organisation, with NHS/HSC patients or with NHS/HSC staff, then you should contact the local NHS/HSC R&D office as early as possible. They will be able to offer advice on whether the project requires management permission within the Research Governance Framework for Health and Social Care. Local NHS/HSC R&D departments now oversee research management and management of resources for research rather than approvals.
Contact details for NHS R&D offices are available on the NHS R&D Forum website. [http://www.rdforum.nhs.uk/content/](http://www.rdforum.nhs.uk/content/)


Other projects within the NHS not classified as research will normally require some other form of approval from the organisation(s) undertaking or hosting the project depending on local arrangements. If the project is audit, service evaluation, public health surveillance, or some other type of non-research activity, such as case study, system/equipment testing or satisfaction survey, you should contact the clinical governance office of your local NHS organisation to check what other review arrangements or sources of advice apply to the project. For example, there may be standard guidelines on the conduct of clinical audit and service evaluation. The Caldicott Guardian will be a source of advice on the use of patient data.

In the first instance, please refer to the HRA Decision Tools. [http://www.hra.nhs.uk/resources/before-you-apply/is-it-research/#sthash.b5bH66Ou.dpuf](http://www.hra.nhs.uk/resources/before-you-apply/is-it-research/#sthash.b5bH66Ou.dpuf)

Health Research Authority (HRA Approval) is the new process for the NHS in England that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent REC opinion provided through the UK research ethics service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England. This centralised HRA Approval process applies only to the NHS in England. Researchers wishing to conduct research in the NHS in Scotland or Wales (or Health and Social Care (HSC) in Northern Ireland) need to obtain NHS or HSC management permission for each NHS/HSC research site. –


Applicants registered as students whose projects need NHS approval/permission should first seek approval from the University of Derby Research Ethics Committee. Members of staff whose projects require NHS approval should first seek Peer Review of their proposal and inform the Chair of the CREC. They do not then need approval from the CREC prior to submission through Integrated Research Application System (IRAS). Lead researchers should keep the CREC informed about progress and outcomes of NHS applications. All projects requiring NHS Ethics approval need to be signed off by the Head of Department on behalf of the University of Derby who acts as the sponsor. Staff or student researchers whose projects
do require NHS ethical approval as above should request NHS approval through the HRA which is conducted through the on-line application system IRAS.

http://www.hra.nhs.uk/resources/applying-for-reviews/integrated-research-application-system-iras/

Where University of Derby staff are involved as partners in collaborative research project, led by another research organisation that require NHS ethical approval they do not also need University of Derby approval. A copy of the approval letter for such project needs to be sent to the relevant University of Derby College Research Ethics Committee Chair.

Once NHS ethical approval and R&D management permission has been received, a letter of confirmation from each needs to be sent to the relevant University of Derby College Research Ethics Committee. Approval letters should also accompany final submission of the research project if it is a student conducting the research.

More information can be found from the Health Research Authority at the following website http://www.hra.nhs.uk/

15. International Research projects with ‘vulnerable’ participants
International students may wish to undertake research with groups who might be perceived as vulnerable groups; generally children or vulnerable adults. UK students are able to provide assurance of their suitability to undertake such work through the Disclosure and Barring Service (or its equivalent within the UK). Similar checks are not however available to international students undertaking work in international contexts or within the UK. In these circumstances research supervisors need to be provided with appropriate evidence of a student's character and criminal record. In many countries this can be evidence through what is commonly known as a 'Certificate of Good Conduct' (CoGC) but has many different names including Certificate of Clearance (COC) and Certificate of no Criminal Conviction. The relevant country's Embassy is a good source of advice.

16. Research projects conducted in a language other than English
Students of the University of Derby are required to submit all their work in English. However some students will want to undertake research in languages other than English. Such students should be advised that all their research tools, written evidence (such as transcripts and survey data), and analysis should be translated into English. Further, they should have a University of Derby approved adviser who is able to verify the accuracy of the translation and who can affirm that the research process is appropriate within the context of local culture and legislation.
17. On-line research

Many of the ethical issues which researchers need to consider and address prior to commencing research online require them to adopt similar ethical frameworks and practices to those employed in onsite research, but the internet also opens up new ethical challenges. It is therefore important that all projects identify, address, justify and reflect upon the specific ethical challenges they present and do not merely and uncritically adopt strategies utilised by other online researches which may have been conducted in different circumstances, cultures and disciplines. The four issues which often arise within the context of online research relate to privacy, informed consent, assurance of confidentiality or anonymity, and legal issues (such as copyright and data storage). A University of Derby guidance note on Online Issues in Ethical Research is available on the intranet,