FACULTY OF SCIENCE, AGRICULTURE AND ENGINEERING

Procedure for the Ethical Approval of Research

1. **Introduction and Context**

University Ethics Committee has delegated responsibility for the ethical approval of research to Faculties. It is a requirement of research councils and other funding bodies that HEIs demonstrate proper consideration of ethical approval.

All staff and students (UG, PGT and PGR) planning to undertake research must follow one of the processes as outlined below, whether or not the project is internal, external, funded or unfunded.

There are three types of research requiring ethical approval:

**Type 1**: Research involving:

- human subjects in a non-clinical setting, participants who are vulnerable or require the cooperation of a gatekeeper, using (but not limited to) questionnaire/survey, experiments, observational studies, covert observational studies, administration of drugs or other substances, collection of fluid or other samples.
- Use of sensitive economic, social or personal data

This requires internal Faculty approval, the process for which is outlined below in section 3.

**Type 2**: Research involving NHS patients/relatives/staff/access to data, organs or other bodily material of past and present NHS patients/use of NHS premises/facilities or vulnerable people in a clinical setting unable to make their own decisions.

This requires external ethical approval from the National Research Ethics Service (NRES).

**Type 3**: Research involving the use of live vertebrate animals or other organisms covered by the Animals (Scientific Procedures) Act.

This requires internal ethical approval from the University Ethical Review Committee, plus Home Office licences where appropriate.

2. **Governance of the Ethical Approval of Research**

A Faculty Ethics Committee has been convened, chaired by the Dean of Research and supported by the Deputy Head of Administration who will assume the role of Faculty Ethics Coordinator. To ensure a broad spread of expertise and ownership for implementation at an academic unit level, in the first instance the other members are Directors of Research and, to cover the teaching remit, the Deans of Undergraduate and Postgraduate Studies. The membership will be reviewed annually.

Faculty Ethics Committee will operate mainly as a virtual committee in reviewing applications, but will meet at least once a year to review operations, consider a summary of preliminary ethical assessment forms/ethics approval applications and compile an annual report to University Ethics Committee. The submission of an annual report, through Faculty Steering Group, to the University Ethics Committee, will provide (a) a brief statement of the Faculty arrangements for consideration of the ethical issues in research; (b) a list of those activities where ethical consideration has been required; and (c) an indication of the problems which have been referred directly to the University Ethics Committee for their resolution. In addition, the University Ethics Committee may call for papers in individual cases as part of its auditing process. Training is arranged for all members, and such sessions are tailored to SAgE disciplines.

It is important to note that while responsibility for the ethical approval process lies with the Chair of the Faculty Ethics Committee, **the responsibility for ensuring the ethical conduct of research and for compliance with the established procedures lies with each individual investigator**.
3. **Procedure for the Approval of Type 1 Research**

i) **Preliminary stage before the proposed research is undertaken:**

- **Staff** planning to undertake research should complete the Preliminary Ethical Assessment form and submit it to the School Ethics Coordinator (your School Administrator/Manager) and copied to the Faculty Ethics Coordinator (Jo Mayne). For projects which are externally funded a copy should also be submitted to the University Grants and Contracts liaison person for your academic unit alongside the Blue Form at the point at which the application to the external funding body is lodged. *The preliminary ethical assessment form must be completed for every project.*

- **PGR students** should complete their normal Project Approval form as this already includes the Preliminary Ethical Assessment form. If full ethical approval is required, PGR students should then follow the procedure in section 3iii) below. Project Approval forms should be completed within 9 months of the commencement of the student's research degree programme.

- **UG/PGT students** will be asked by the relevant module leader to complete the Preliminary Ethical Assessment form for all modules involving research projects. The module leader should then review the forms to ensure that ethical aspects of the research have been considered. If the planned research does not require full approval, the module leader should retain the batch of preliminary ethics assessment forms together with other formal module information. If full ethical approval is required, UG/PGT students should then follow the procedure in section 3iii) below.

ii) **When does research requiring full ethical approval have to be considered?** *(i.e. if the answer to any of the questions in the table within question 2 of the preliminary ethical assessment form/project approval form is ‘yes’)*

- For **staff** research requiring full ethical approval, this is normally if and when the project is awarded unless the Grants and Contracts team notify the PI at submission of the preliminary ethics assessment form that the funder’s terms and conditions require earlier ethical approval.

- For **PGR students**, this will be an immediate requirement as part of their project approval.

- For **UG/PGT students**, this will be an immediate requirement before they are able to begin their research.

iii) **Process for requesting full ethical approval:**

Where full ethical approval is required, the Ethics Approval Application Form must be completed and submitted to the Faculty Ethics Coordinator (Jo Mayne) and copied to the University Insurance and Risk Manager (Mark Jackson) who will address any issues regarding insurance/indemnity arising from the proposed research. Any proposed consent forms/participant information sheets should be submitted to the Faculty Ethics Coordinator together with the full ethics application. For funded applications, the form should also be copied to the Grants and Contract team.

Once received by the Faculty Ethics Coordinator, the form will be circulated for review to 2 members of the Faculty Ethics Committee (one more closely related to the discipline area; the other not related to the discipline) and returned with any comments/issues. Members are empowered to require amendments in the application or research protocol in order to address any particular areas of ethical concern. Their comments and concerns, if any, will be returned to the applicant for consideration and response. Provided that there are no remaining ethical issues, formal approval will be given by the Chair (or nominee) of the Faculty Ethics Committee and communicated to the applicant. The timescale for the process would normally be within 2 weeks of initial receipt. All applications will be tracked and monitored by the Faculty Office. The Faculty Ethics Committee may also refer particular cases to the University Ethics Committee if a decision cannot be reached and is obliged to consult with the University Ethics Committee where the research might create a precedent, or the research topic and methodology are particularly sensitive. The applicant may appeal to the University Ethics Committee against a decision by the Faculty Ethics Committee not to grant ethical approval for a project.

4. **Links to Further Information**

Information and forms relating to the ethical approval of research can be found at: [http://www.ncl.ac.uk/business-directorate/ethics/index.php](http://www.ncl.ac.uk/business-directorate/ethics/index.php)