



UNIVERSITY of LIMERICK

OLLSCOIL LUIMNIGH

RESEARCH OFFICE

Operational Guidelines for University of Limerick
Research Ethics Governance Committees

1. INTRODUCTION

- 1.1 The University of Limerick Research Ethics Governance Committee (ULREG) is concerned with research ethics governance, a process which sets standards for research ethics, defines mechanisms to deliver these standards and describes associated monitoring and assessment arrangements
- 1.2 ULREG is supported in this role by Faculty level/Specialist research ethics committees (RECs) (Fig. 1: Research Ethics Committee Structure). All research ethics applications are submitted to and considered by the relevant REC. Any subsequent appeal that may arise is referred to ULREG for final decision.

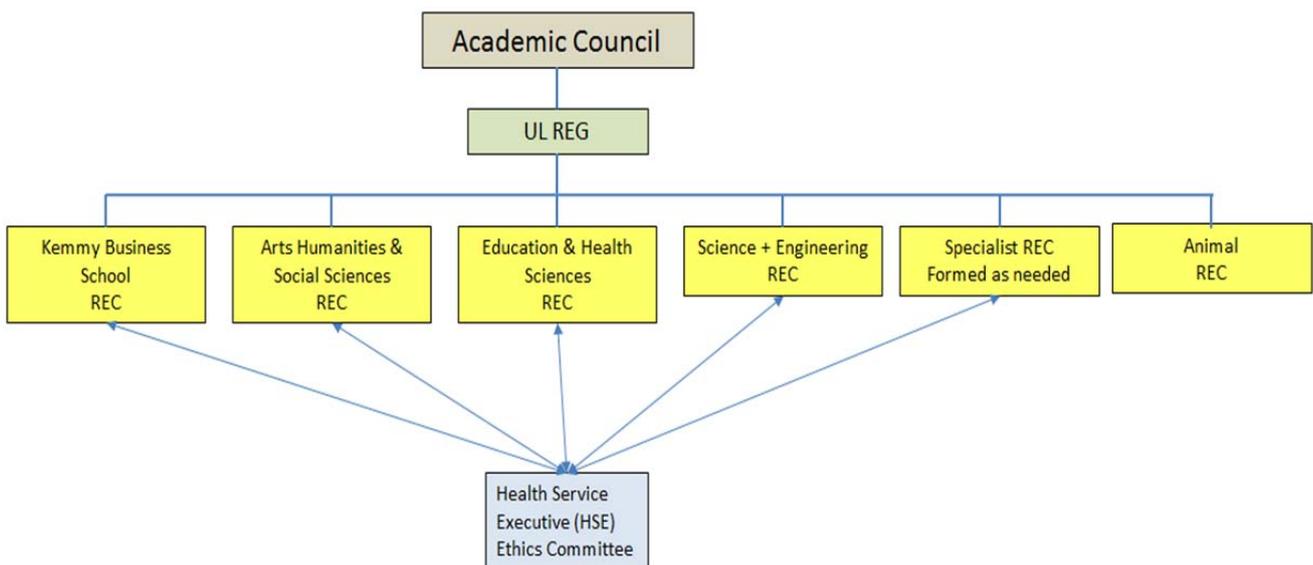


Figure 1 Research Ethic Committee Structure

- 1.3 The Chairperson of ULREG will be independent and will be chosen from individuals with appropriate expertise external to the University. The Chairperson will be appointed by Academic Council on the nomination of the President.
- 1.4 The development and maintenance of appropriate policies and procedures regarding research ethics governance is essential to ensure the University undertakes high quality and ethically sound research that stands up to the standards set by evolving and new legislation such as the EC Clinical Directive and the Human Tissue Act. Additionally, many research awarding bodies now require assurances at both application and award stage that projects have, where necessary, been approved by an institution's ethics committee and that research ethics governance structures and policies are in place. The University of Limerick is committed to achieving the highest academic and ethical standards in all its research activities. Thus ULREG will seek to follow best practice in terms of research ethics governance with its members participating in National and International Research ethics bodies.

1.5 These Operational Guidelines for research ethics governance set down the terms of reference for ULREG and the RECs, provide reference to the application methods for ethics approval and guidelines for specific research fields.

2. TERMS OF REFERENCE OF THE UNIVERSITY OF LIMERICK RESEARCH ETHICS GOVERNANCE COMMITTEE (ULREG)

2.1 Constitution

2.1.1 ULREG acts on behalf of Academic Council and reports to Academic Council on matters within its remit.

2.1.2 ULREG has a major role in ensuring proper research ethics governance within the University of Limerick and is responsible for the development, implementation and evaluation of policy and procedures related to University of Limerick research ethics governance.

2.1.3 The University of Limerick's Academic Council recognises the significant contribution to the University's research ethics governance made by an efficient and effective ULREG.

2.1.4 The Academic Council pledges its full support to ULREG in discharging its authorities and responsibilities. Further, it respects the independence of ULREG and undertakes to provide adequate resources to enable the Committee to properly discharge its function.

2.1.5 The Terms of Reference of ULREG will be reviewed by the Academic Council from time to time and updated as appropriate, with a view to ensuring that the Committee's responsibilities regarding the matters within its remit continue to be effectively discharged.

2.2 ULREG is charged with the development, evaluation and monitoring the implementation of policies and procedures in relation to all aspects of research ethics governance including:

- To develop/endorse and promote a University Research Code of Conduct;
- To develop guidelines of good practice in research ethics within the University and provide for their publication in the Operational Guidelines for University Research Ethics Governance Committees hereafter referred to as Operational Guidelines;
- To develop operational structures for research ethics approval within the University and provide for their publication in the Operational Guidelines;
- The development as required of other policy and guidelines documents related to research ethics governance;
- To consult and advise University management, staff and students with regard to research ethics governance;

- To develop policy and procedures for HSE related research ethics matters in consultation with HSE representatives and existing structures.
- 2.3 Evaluation
- To evaluate operational structures for research ethics approval within the University;
 - To initiate and undertake Quality Audits of the RECs to ensure compliance with agreed policies and procedures and comment and make recommendations on :
 - The application of the ethical principles in decision making;
 - The process, volume and speed of decision making;
 - The feedback to applicants;
 - The review of Research Completion Reports on Approved Applications.
- 2.4 Monitoring: To monitor the implementation of operational structures for research ethics approval within the University;
- To promote guidelines of good practice in research ethics within the University and monitor adherence to those guidelines;
 - To act as the final body of appeal and final decision maker on any disputed matter concerning research ethics;
 - To promote awareness of all aspects of research ethics governance among the University community;
 - To support researchers with ethics issues across all fields of research.
- 2.5 ULREG may request at any time data from the RECs including:
- The number of applications submitted for review, those approved, those provisionally approved and subsequently approved by the Chair and finally those declined;
 - The number of HSE approved projects and their details.
- 2.6 ULREG will provide oversight to ensure that the reporting requirements as set out in the Operational Guidelines are complied with in a timely fashion.
- 2.7 ULREG may establish such and so many RECs as it deems necessary for effective research ethics governance and provide for the structure of these RECs in the Operational Guidelines.
- 2.8 ULREG will make an annual written report on its activities to Academic Council and will report regularly to Academic Council on its activities, issues, related recommendations and approvals as required.
- 2.9 Following approval by Academic Council, ULREG will arrange for the publication of its Annual Report in accordance with the provisions as set down in the Operational Guidelines.

- 2.10 ULREG when requested will present research ethics related issues to Governing Authority.
- 2.11 ULREG will convene a minimum of 4 times a year, with additional meetings scheduled as required.
- 2.12 A quorum shall consist of 4 members, which must include the Chairperson/Vice Chairperson and Corporate Secretary/Information & Compliance Officer.
- 2.13 All policies developed by ULREG will be submitted to Academic Council for approval in the first instance. Academic Council will submit these policies as required to Governing Authority for approval. Any amendments to such policies by ULREG must also be submitted to Academic Council for approval.
- 2.14 Any changes to the ULREG Terms of Reference will be approved by Academic Council.

3. COMPOSITION OF ULREG

- 3.1 Academic Council will approve the composition of ULREG and will appoint those who are not ex officio members. The composition of ULREG will be:
 - A Chairperson who is not an employee/student of the University;
 - Dean of Graduate School (Vice Chairperson) (ex officio);
 - Chairs of the RECs (ex officio) or their alternate;
 - President of the Postgraduate Students' Union (ex officio) or alternate;
 - Corporate Secretary (ex officio) or alternate (Information & Compliance Officer, ex officio);
 - A member who is trained in or has practical experience in the area of research ethics, as approved by Academic Council from time to time, on the nomination of ULREG.
- 3.2 The Chairperson will be appointed by Academic Council on the recommendation of the President of the University of Limerick for a 3 year term, renewable by Academic Council, for one further term, on the recommendation of the President.
- 3.3 Members of ULREG will be listed on the University website.
- 3.4 ULREG members shall be offered induction and training on an on-going basis as appropriate by the Dean of Graduate School.
- 3.5 ULREG may co-opt internal and/or external experts as deemed necessary for specific situations for defined periods subject to approval of a majority of the members of ULREG present at the meeting at which the proposal for co-option is made.

4. MEETINGS of ULREG

- 4.1 ULREG members or their alternates are expected to attend ULREG meetings.
- 4.2 Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.
- 4.3 Reports of the RECs will be taken as a standing order at the start of each meeting.
- 4.4 All matters arising will be addressed with completed items being noted, and incomplete items becoming matters arising for the subsequent meeting.
- 4.5 Draft meeting minutes will be prepared and circulated to the Committee members and alternates in a timely manner.
- 4.6 Decisions made will be recorded in the meeting minutes with the action that need to be taken and the person responsible for the action.
- 4.7 Extraordinary meetings may be held by ULREG regarding appeals and applications that are deemed outside the expertise of a REC.

5. RESEARCH ETHICS COMMITTEES (RECs)

- 5.1 The RECs are responsible for the implementation of policy and procedures related to research ethics and as such, they report to ULREG. The RECs have the authority to consider the ethics of proposed research projects and to provide research ethics approval/disapproval. In undertaking this role, the RECs aim to ensure that research is conducted according to best practice for ethics standards in research. In keeping with this, the RECs aim to safeguard the health, welfare, dignity and rights of human participants, animals and researchers in order to minimise risk to participants, researchers, third parties, and to the University itself. The RECs are deemed to facilitate, not hinder, valuable research and to protect researchers from unjustified criticism and/or legal action.
- 5.2 The RECs are deemed to include the Faculty Research Ethics Committees and the Animal Research Ethics Committee and any other specialist REC that may be established from time to time by ULREG.

5.3 Animal Research Ethics Committee

5.3.1 The remit of the Animal Research Ethics Committee (Animal REC) is as set out in 5.1 and shall provide a thorough, expert, robust and independent ethics assessment of scientific work involving animals by UL personnel. In this regard, the Animal REC will be guided by the requirements as set out by the Health Products Regulatory Authority (HPRA, formerly the Irish Medicines Board) and will ensure that research conducted by UL researchers is in line with the ethos of the University. Notwithstanding its independent role, the Animal REC will also provide advice and guidance to UL personnel on animal ethics issues and on the legislative requirements of animal licensing at national level which is overseen by the HPRA.

5.4 ULREG pledges its full support to the RECs in discharging the authorities and responsibilities contained in this operational guidelines.

5.5 Terms of Reference of the RECs

5.5.1 Evaluation of Ethics Applications for Research Projects:

- Adjudicate on whether research projects are deemed ethical;
- Liaise with the HSE if required on applications relating to University research approved by the HSE Ethics Committee;
- Co-opt internal and/or external experts to the REC as deemed necessary for specific situations for defined periods;
- Comment to ULREG on procedures and policy;
- Forward applications to ULREG that are deemed outside the expertise of REC.

5.5.2 Development of Policy and Procedures:

- To develop policy and procedures for HSE related research in conjunction with ULREG;
- To develop policy and procedures for specific area related to research within the Faculty in conjunction with ULREG;
- To develop procedures for the efficient operation of REC.

5.5.3 Implementation of Policies and Procedures:

- To promote a University Research Code of Conduct;
- To adjudicate ethics issues of applications;
- To adhere to guidelines of good practice in research ethics within the University;
- To facilitate an appeal of the committee's decision to ULREG;
- To facilitate any quality audit as defined by ULREG/ University.

5.5.4 Evaluation of Policies and Procedures:

- To provide feedback to ULREG on operational structures for the development of research ethics approval within the University;

- To provide feedback to ULREG as required on the development of other policy and guidelines documents related to research ethics governance;
- To provide feedback to ULREG on the decision making process within each REC on:
 - The application of the ethics principles in the decision making;
 - The process, volume and speed of decision making;
 - The feedback to applicants;
 - The review of research completion reports on approved applications.

5.5.5 Reporting:

- Each REC will make a written report on its activities to ULREG using the template in Appendix 1, at least 2 weeks prior to the ULREG meeting;
- Each REC will report details relating to appeals on decisions, any queries/clarifications of note, any applications outside the expertise of the REC committee or those requiring legal interpretation for decision by ULREG.

5.6 Composition of the Faculty RECs

5.6.1 Each Dean of Faculty will appoint the members and alternates to their relevant Faculty REC as follows:

- A Chairperson and an alternate;
- A member of each Department of the Faculty and alternates;
- Representation from outside the Faculty;
- Postgraduate student.

5.6.2 Composition of the Animal REC

5.6.2.1 The ULREG Committee will appoint the members and alternates to the Animal REC as follows:

- A Chairperson with experience in the subject area;
- Up to four members from within/outside the University who are competent in the specialist area, to include a member who is trained in or has practical experience in the area of research ethics.

5.6.3 One or more of the members of the Faculty RECs and Animal REC must be trained in ethics and all REC members shall be offered induction and continuing training as appropriate.

5.6.4 The Chairperson of the Faculty RECs and Animal REC will be appointed for a term of 3 years, with 2 terms in office being the norm.

5.6.5 Internal and/or external experts may be co-opted to a REC as deemed necessary for specific situations for defined periods. Co-options are with the majority approval of the members of the REC present at the meeting at which the proposal is made.

5.6.6 Members and alternates of the RECs will be listed on the University website.

5.7 Meetings of RECs

5.7.1 Each REC will convene a meeting every month with a summer suspension if warranted; additional meetings may be scheduled as required.

5.7.2 REC members are expected to attend the meetings.

5.7.3 A quorum shall consist of the Chairperson and at least half of the remaining members. However, it is assumed that where alternatives are appointed, the full membership should sit in all but exceptional cases.

5.7.4 Non-members may be invited to attend meetings as deemed necessary for specific situations. Invitations are with the majority approval of the members of the REC present at the meeting at which the proposal is made.

5.7.5 Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.

5.7.6 All matters arising will be addressed with completed items being noted, and incomplete items becoming matter arising for the subsequent meeting

5.7.7 Draft meeting minutes will be prepared and circulated to the REC members and alternates in a timely manner

5.7.8 Decisions made will be recorded on the meeting minutes with the action that need to be taken, and the person responsible for the action.

5.7.9 Applications deemed to be outside the expertise of a REC or requiring a specific legal position will be passed to ULREG.

6. SPECIALIST RESEARCH ETHICS COMMITTEES

6.1 Specialist Research Ethics Committees have the responsibility for the implementation of policy and procedures related to a specific topic of research ethics and as such it reports to ULREG. Such committees will be formed for a specific purpose.

6.1.1 ULREG pledges its full support to Specialist RECs in discharging the authorities and responsibilities contained in this operational guidelines.

6.2 Terms of Reference of Specialist Research Ethics Committees

- 6.2.1 Specialist Research Ethics Committees have the authority to:
- Implement ULREG and University policies and procedures in relation to all aspects of research ethics;
 - Adjudicate on whether research programmes in the specialist area are deemed ethical;
 - Liaise with the HSE if required on applications relating to University research approved by the HSE Ethics Committee;
 - Comment to ULREG on procedures and policy.
- 6.2.2 A Specialist Research Ethics Committee will make a written report on its activities to ULREG using the template in Appendix 1, at least 2 weeks prior to the ULREG meeting.

6.3 Composition of Specialist Research Ethics Committees

- 6.3.1 The ULREG Committee will appoint the members to a Specialist Research Ethics Committee, taking external advice if necessary. A Specialist Research Ethics Committee will consist of:
- A Chair with experience in the subject area
 - Up to 4 members within or outside the University competent in the specialist area
- 6.3.2 One or more of the members of the committee must be trained in ethics.
- 6.3.3 Internal and/or external experts may be co-opted to the Specialist Research Ethics Committee as deemed necessary for specific situations for defined periods. Co-options are with the majority approval of the committee.

6.4 Meetings of Specialist Research Ethics Committees

- 6.4.1 Specialist Research Ethics Committees will be convened as necessary to complete the business they were set up for.
- 6.4.2 A quorum shall consist of the Chair, and at least half of the assigned members.
- 6.4.3 Non-members may be invited to attend meetings as deemed necessary for specific situations. Invitations are with the majority approval of the committee.
- 6.4.4 Meeting agendas will be prepared and provided in advance to members, along with appropriate briefing materials.
- 6.4.5 All matters arising will be addressed with completed items being noted, and incomplete items becoming matter arising for the subsequent meeting if relevant.

- 6.4.6 Draft meeting minutes will be prepared and circulated to the committee members in a timely manner.
- 6.4.7 Decisions made will be recorded on the meeting minutes with the action that need to be taken, and the person responsible for the action.
- 6.4.8 As a Specialist REC may convene only once, or at irregular intervals, the Chairperson will be responsible for ensuring that all action items are concluded, prior to the cessation of the committee.

7. HSE RESEARCH ETHICS COMMITTEE

- 7.1 Research applications that have been approved by the HSE Research Ethics committee must be noted by the relevant REC of the Principal Investigator¹/Supervisor².
- 7.2 Approval letters should be copied to the recording secretary of the REC, with the successful applications being noted as approved on the University of Limerick Research Ethics Governance Committee Report Form (Appendix 1) with the Faculty acronym being replaced by HSE.

8. RESEARCH ETHICS PRINCIPLES FOR RESEACHERS

- 8.1 A high standard of research ethics principles are essential for all researchers. These principles aim to protect the dignity, rights, safety and well-being of all actual or potential research participants. A summary of these research ethics principles are set out in the University of Limerick 'Procedures for Research Ethics Approval'.

9. PROCEDURES FOR RESEARCH ETHICS APPLICATIONS

- 9.1 The University of Limerick 'Procedures for Research Ethics Approval' provides comprehensive information on making a Research Ethics application. These Procedures along with additional REC guidelines and ethics application forms are available at www.ul.ie/researchethics.

10. INSURANCE COVER FOR RESEARCH

- 10.1 Confirmation of insurance cover is a requirement for all research ethics applications submitted to a REC for consideration. A Principal Investigator/Supervisor must ensure the necessary insurance cover is in place as part of their application. Details of the University's insurance cover and the University's 'Guidelines on Insurance Cover for Research' are available at www.ul.ie/insurance.

¹ **Principal Investigator:** A Principal Investigator is an employee of the University who has primary responsibility for the design, implementation, completion and management of a research project.

² **Supervisor:** A Supervisor is an employee of the University who is assigned to a postgraduate research candidate at the time of their commencement of a postgraduate research project. The supervisor has responsibilities relating to the postgraduate's academic and research activities as described in Section 5 of the University of Limerick's Handbook of Academic Regulations and Procedures (Research Postgraduate Academic Regulations).

11. PROCESSING AND ADJUDICATION OF RESEARCH ETHICS APPLICATIONS

- 11.1 The decisions of the REC are guided by the following set of generic ethics principles:
- Respect for the dignity, worth and self-determination of all participants;
 - Responsibility to the research participant and to society;
 - The conducting of research which is within the competence of the researcher;
 - Whether the research has non-human ethical implications (Genetic modification, animal Military etc.).
- 11.2 In addition, the REC may also take into account any codes of practice or guidelines which apply to the discipline. The decision making process of the REC is governed by the following factors:
- Transparency and accountability of ethics decision making;
 - Awareness of the limitations of the competence of the REC;
 - Obligation to accumulate and disseminate a knowledge-base of ethics issues and procedures to inform future ethics decision making.
- 11.3 The REC may approve such applications where, in its own judgement, the ethics issues that arise in the research and decision making process have been addressed adequately.
- 11.4 Where it is considered appropriate, a REC may invite Principal Investigators/Supervisors to attend a REC meeting and participate in discussions about their proposal. RECs should also accommodate reasonable requests from Principal Investigators/Supervisors to participate in discussions about their proposal. Principal Investigators/Supervisors may not be present when the REC is making its decision.
- 11.5 In the event that the Principal Investigator/Supervisor for a research project is also a Chairperson on a REC, sign-off approval for ethics regarding the research project should be undertaken by another member of the REC.
- 11.6 It is desirable to adopt a consistent approach to granting or declining approval of a proposal. It is recommended that the following terminology be used in communicating the decision of the REC to an applicant:
- i. **Approved**, the applicant may conduct the research as outlined in the research proposal submitted to the REC;
 - ii. **Provisionally approved**, subject to recommended revisions to the proposal or answers to questions posed to the applicant. The revisions and/or answers must be resubmitted to the REC and/or for Chair's Action before receiving final approval. No research may be conducted prior to receiving final approval;

- iii. **Approval declined**, detailed reasons for declining approval should be forwarded to the applicant, with or without an invitation to resubmit a substantially altered proposal for reconsideration.

11.7 The REC decision should be communicated to the applicant in writing within two weeks of the meeting at which the decision was taken.

11.8 All decisions should be recorded on the University of Limerick Research Ethics Governance Committee Report Form (Appendix 1), and reported to ULREG.

11.9 REC Chairperson Approval

11.9.1 In the context of an application viewed by a REC and given the designation “provisionally approved”, the relevant REC Chairperson can independently consider whether the changes recommended by the REC have been applied to the REC Application and give final approval to the application. This decision will be reported by the Chairperson at the following meeting of the REC. This should then be recorded on the University of Limerick Research Ethics Governance Committee Report Form (Appendix 1).

11.10 Sign-off of ethics approval in the event that Principal Investigator/Supervisor is also a REC Chairperson

11.10.1 In the event that the Principal Investigator/Supervisor for a research project is also a REC Chairperson, sign-off approval for ethics regarding the research project must be undertaken by another member of the REC.

12. APPEAL OF AN ETHICS APPLICATION DECISION

12.1 An appeal of a decision made by a REC should be made in writing to the Chairperson of ULREG and copied to the recording secretary, outlining the grounds of the appeal, within 10 working days of the decision being relayed to the applicant.

- The appeal will be heard at the next scheduled meeting of ULREG, unless an extra ordinary meeting is required (as decided by the Chairperson of ULREG);
- The decision of the ULREG will be relayed to the REC/ Chairperson and the applicant, within 5 working days of the meeting;
- The decision of ULREG will be final.

13. REC RECORDS MANAGEMENT & RETENTION

13.1 All documentation and communications of ULREG and the RECs must be dated, filed and archived appropriately. The REC Chairperson for each REC Committee will be responsible for the archiving of all relevant documentation. Documents must be stored in a secure place where there is adequate protection against fire. Electronic records and backups of all documents must be maintained on password protected computers. A statement is required defining the access and retrieval procedure (including authorised persons) for the various documents, files and archives, this can be found on the individual ethics sites of the Faculties and the Graduate School.

13.2 Documents to be filed and archived include, but are not limited to:

- All material submitted by an applicant;
- All correspondences by REC members with applicants or concerned parties regarding applications, decision and follow-up;
- Copies of decisions & any advice and/or requirements issued to applicants;
- The agenda of all ULREG and REC meetings;
- The minutes of all ULREG and REC meetings which should include members present, 3rd parties present, time, date & place of meeting;
- Annual reports of ULREG to the Academic Council of the University;
- Risk assessment procedures;
- Research completion forms where applicable.

13.3 Retention of ethics application forms

13.3.1 Ethics application forms may be received in hard and/or soft copy by the RECs. Once a consistent filing system is in place which undergoes regular backup and has adequate security provision, there is no requirement for a signed hard copy to be held by the RECs as a scanned version is deemed adequate for evidence purposes.

13.3.2 The retention time for ethics application forms by the RECs is as per the University's Records Management & Retention Policy.

14. QUALITY AUDITS

14.1 Independent Quality audits of Research ethics governance will take place on a 5 year cycle.

15. TRAINING

15.1 An annual ethics training program is available to all staff, via the Graduate School's generic and transferable skills program.

APPENDIX 1

The following table is the report template for REC meetings. The Template forms the basis of the REC's report to ULREG, and should be forwarded to the ULREG recording secretary together by soft copy following the REC meeting.

The decisions can be noted with a tick in the appropriate box:

- A - Approved
- PA - Provisional approval
- D - Declined

Comments should be made in regard to the ethical reasons for approval (if needed) provisional approval or declining the application.

Application numbers

'Application Number' be recorded in the following format –
'year_month_project no._Faculty'

e.g. for an Arts Humanities & Social Science Faculty application in December 2012 the first application will be coded:

'2012_12_001_AHSS'.

The second on the list '2012_12_002_AHS', etc.

For an Education & Health Sciences Faculty application in August 2011 the first application will be coded:

'2011_08_001_EHS'.

The second on the list '2011_08_002_EHS', etc.

For a Kemmy Business School application in March 2014 the first application will be coded:

'2014_03_001_KBS'.

The second on the list '2014_03_002_KBS', etc.

For a Science and Engineering Faculty application in October 2015 the first application will be coded:

'2015_10_001_S+E'.

The second on the list '2015_10_002_S+E', etc.

Approvals from the Animal REC will be noted with an AREC acronym, HSE approvals will be noted with a HSE acronym and Specialist Committees as SREC

