

Procedure for Granting Ethical Approval

Classification:	Procedure
Version Number:	1.2
Status:	Approved
Approved by:	University Research Committee
Approval Date:	16/01/2023
Effective from:	16/01/2023
Next Review Date:	16/01/2026
Document Author:	Dr Danielle Smith
Document Owner:	Dr David Richards, Pro-Vice Chancellor (Research & Enterprise)
Department/Contact:	Research Governance
Summary:	This document sets out to articulate the ethical principles by which all research activities must abide.
Scope:	This policy applies to all staff and students conducting research associated activities on behalf of or in auspice of the University of Hull as described in the policy
Collaborative provision:	Please state whether this document is applicable to the university's collaborative partners: ☒ Mandatory ☐ Not mandatory
Assessment: (where relevant)	☐ Equality Assessment ☒ Legal via Solicitor's Office ☐ Other, please specify:
Consultation: (where relevant)	☐ Staff trade unions via HR ☐ Students via Hull University Union ☐ Any relevant external statutory bodies
Relevant legal / regulatory frameworks:	Data Protection Act 1988; Mental Capacity Act 2005; Human Tissue Act 2004
Related documents:	Code of Good Research Practice; Procedure for Granting Ethical Approval.
Published location:	University website's Policies and Procedures page; Research Governance SharePoint page
Document Communication and Implementation Plan:	All printed versions of this document are classified as uncontrolled. A controlled version is available from the University website.
All printed or downloaded versions of this document are classified as uncontrolled. A controlled version is available from the university website.	

**This document is available in alternative formats from
researchgovernance@hull.ac.uk**

Click or tap here to enter document title.

Table of Contents

SECTION A INTRODUCTION.....	3
1. Purpose	3
2. Scope	3
3. Collaborative Provision	3
4. Why are research ethical review committees important?	3
5. Related Documents	4
SECTION B RESPONSIBILITIES	4
6. Dean.....	4
7. Researchers	4
8. PhD Student Supervisors	4
9. Faculties	4
10. Faculty Ethics Officer	5
11. Chair of Faculty Ethics Committee.....	5
12. Faculty Ethics Committee	5
13. College of Reviewers.....	6
14. Special Advisory Group.....	6
15. University Ethics Committee	6
SECTION C: PROCEDURE FOR OBTAINING ETHICAL APPROVAL	7
16. Pre-approval for Staff and PhD Researchers	7
17. Obtaining Approval.....	7
18. Post Approval.....	9
19. Projects involving external partners.....	10
SECTION D: BREACHES OF THE POLICY	11
20. Breaches	11
APPENDIX 1: ETHICS APPLICATION PROCEDURE FOR STAFF AND POSTGRADUATE RESEARCH APPLICANTS.....	12
APPENDIX 2: GENERAL APPLICATION PROCESSING FOR LOW AND HIGH RISK ETHICS APPLICATIONS	13

Procedure for Granting Ethical Approval

SECTION A INTRODUCTION

1. Purpose

1.1 The aim of this University document is to explain the procedure to be followed for granting ethical approval to research proposals. The procedure is based on two principles:

- there must be explicit discussion, at an appropriate level, of matters of ethical concern before a project goes ahead;
- there must be a clear framework of responsibility.

1.2 It aims to set out clearly the roles and responsibilities of all involved in the approval process to ensure fair and proportionate review of research proposals conducted at or under the auspices of the University of Hull.

1.3 For the purpose of this document:

- The University of Hull will be referred to as “The University”; and
- **must** infers mandatory; **may** infers desirable; **should** infers advisable.

2. Scope

2.1 The University of Hull has a duty of care to all staff and students registered at the University, participants in the research, the wider public community and the environment that may be impacted by the research. This Policy is of direct relevance to all those who host, conduct, participate, manage, professionally support or disseminate the results of research conducted on behalf of the University. All commercial and contract research conducted on University premises or by University staff or students is subject to the principles and ethical standards described in this policy.

3. Collaborative Provision

3.1 University of Hull collaborative providers are expected to have their own procedures in place that adhere to the principles and ethical standards of this policy.

4. Why are research ethical review committees important?

4.1 Some research involves risk, potentially to the participant, the researcher/s, the environment or the community, and of varying degrees.

4.2 The principles of beneficence and non-maleficence of the research should be impartially applied to all the parties involved.

4.3 Ethics Committees must be assured that the risk, burden and intrusions are minimised and justified for the benefit of the participants, science, environment and the community.

4.4 Reviews by Ethics Committees should complement the researchers’ own ethical consideration and consideration by other parties involved in the research for example

methodologists, statisticians, academic and commercial collaborators.

5. Related Documents

- 5.1 This policy should be read in conjunction with the University's Research Ethics Policy and the Code of Good Research Practice.

SECTION B RESPONSIBILITIES

6. Dean

- 6.1 The Dean of a Faculty is responsible for oversight of research ethics within his or her faculty. This includes ensuring the appropriate application of ethical principles in research by all staff and students involved in research.
- 6.2 The Dean may delegate the responsibility of governance of the research ethics approval procedure to the Associate Dean for Research.
- 6.3 The Dean delegates the authority to grant approval to research ethics applications to the Chair of the Faculty Ethics Committee.
- 6.4 The Dean is responsible for the implementation of the institutional procedure for obtaining and granting ethical approval.
- 6.5 The Dean is responsible for informing University Ethics Committee of the relevant committee structure within the Faculty.

7. Researchers

- 7.1 Researchers must prepare and submit research ethics approval applications for their own research projects, with the exception of undergraduate and taught postgraduate programme research (See Section C for undergraduate and postgraduate taught research projects).
- 7.2 PhD students must prepare all research ethics application for their research with the support and guidance of their project supervisor.

8. PhD Student Supervisors

- 8.1 Supervisors must provide guidance and support to the PhD student to prepare the ethics application including identifying issues of ethical concern, understanding good and ethical research practice and the preparation of the application.
- 8.2 The project supervisor must approve the PhD student's application for submission to the Faculty Ethics committee.

9. Faculties

- 9.1 Faculties are to administer the University procedure and grant ethical approval to research projects undertaken by its own researchers.
- 9.2 Institute-based projects are to apply for ethical approval through the Faculty Ethics Committee of the project PI.
- 9.3 For cross faculty projects, Faculties may request/invite expert members from the College of Reviewers to provide specialist advice on ethical issues. The request should be made by the Faculty Ethics Officer or the Chair.
- 9.4 Associate Dean for Research will be responsible for ensuring that the process of review has been followed appropriately and must sign off the approval after it has been granted.

10. Faculty Ethics Officer

- 10.1 The Faculty Ethics Officer is responsible for communicating any changes in the University procedures and policies to the faculty.
- 10.2 Faculty Ethics officers will be responsible for providing support to researchers to identify issues of ethical concern when requested.
- 10.3 The Faculty Ethics Officer is responsible for triage of all ethics applications to the Faculty Ethics Committee and to assign the application to the appropriate Subject Ethics Officer for confirmation of the risk assignment made by the PI.
- 10.4 For projects identified as involving security sensitive research, Faculty Ethics Officers are first point of contact and are responsible for providing guidance to researchers on the appropriate University approved procedure. Please refer to the Security Sensitive Procedures and Policy, and the Security Sensitive Research Guidance Note for further information.
- 10.5 For research proposals requiring ethical approval from external committees (eg. IRAS, other institutions), the Faculty Ethics Officer will support the PI in directing the application through the appropriate route.
- 10.6 All IRAS applications sponsored by the University will undergo quality-control assessment conducted by Research Governance who will make recommendations to the Chair to approve for submission for the HRA Approval.
- 10.7 Faculty Ethics Officer may be the Secretariat of the Faculty Ethics Committee but not necessarily.

11. Chair of Faculty Ethics Committee

- 11.1 The Chair of the Faculty Ethics Committee is responsible for granting approval of all ethics applications.
- 11.2 The Chair of the Faculty Ethics Committee is responsible for chairing the Ethics Committee meetings, they may delegate in their absence to a Deputy Chair.
- 11.3 For high risk research projects, the Chair will approve the application on recommendation of the quorate Committee.
- 11.4 All Faculty Ethics Committee Chairs will be members of the University Ethics Committee.

12. Faculty Ethics Committee

- 12.1 Each Faculty Research Ethics Committee will have clear terms of reference, must have a least one lay member and three academic members to be quorate, with a minimum of six members in attendance.
- 12.2 Each Faculty Ethics Committees must convene at least three times a year. Extraordinary meetings may be convened as necessary under special circumstances at the request of the Committee Chair.
- 12.3 Each Faculty Ethics Committee will forward the terms of reference annually to the University Ethics Committee that includes the Committee membership.
- 12.4 Each Faculty Research Ethics Committee will provide guidance for members in research ethics and relevant legislation, be minuted by the Secretariat, who is not the Chairperson.
- 12.5 Approval shall be granted by the Chair under the unanimous recommendation of the quorate Faculty Ethics Committee.
- 12.6 Any Committee Member of the Faculty Research Ethics Committee involved in the proposed

research must abstain from the recommendation of the Committee.

- 12.7 The Faculty Ethics Committee Secretary will forward any decisions made by the Committee to the Faculty Ethics Officer who will inform the applicant.
- 12.8 Each Faculty Ethics Committee shall report to the University Ethics Committee annually, to be received by 30 September to the Assistant Secretary of the University Ethics Committee, that includes the following information:
- 12.9 summary of all research misconduct investigations (staff and student);
- 12.10 any extraordinary procedures/process employed during the review of an application; and
- 12.11 the name and initiator of each application and whether approved, referred or rejected by the Committee.

13. College of Reviewers

- 13.1 All Faculty Ethics Committee members are invited to be members of the University College of Research Ethics Reviewers.
- 13.2 Faculties can invite members to the College to function as reviewers only to offer expert subject review.
- 13.3 The Head of Research Excellence, Governance and Impact is responsible for the management of the College.
- 13.4 All Faculties will have access to the College and may invite members as required to review applications.
- 13.5 Reviews provided by the invited member will serve only to provide information for and support the decision of the standard committee members.

14. Special Advisory Group

- 14.1 The Special Advisory Group advises on ethical issues of significant institutional risk but will not have decision-making authority as an entity.
- 14.2 Requests to convene can be made to the Head of Research Excellence, Governance and Impact by the Faculty Ethics Committee Chair, the Faculty Ethics Officer, the Dean of Faculty and/or the Chief Operating Officer.
- 14.3 Members will be selected from the College of Reviewers and the members of the
- 14.4 University Ethics Committee based on the need of the identified elements of concern.

15. University Ethics Committee

- 15.1 The University Ethics Committee is the overarching governance committee that ensures ethical practice of all University activities including research ethics.
- 15.2 The University Ethics Committee shall have clear terms of reference and comprise the Chair of each Faculty Ethics Committees, a Chairperson, at least one lay member to ensure independence and public accountability and be serviced by an Administrator,
- 15.3 The University Ethics Committee shall ensure training is provided for staff and students involved in research on research ethics and relevant legislation.
- 15.4 The Chair of the University Ethics Committee is an ex-officio membership and shall be the Pro-Vice Chancellor for Research.
- 15.5 The University Ethics Committee must normally meet at least three times an academic year,

and have oversight of ethics approval pro-formas.

- 15.6 The University Ethics Committee must report annually to the Council each academic year covering changes to governance procedures, matters that have arisen of institutional concern and all research misconduct investigations.

SECTION C: PROCEDURE FOR OBTAINING ETHICAL APPROVAL

16. Pre-approval for Staff and PhD Researchers

- 16.1 When students, supervisors, or research staff are considering the beginning of piece of research they must consider whether any ethical issues need to be addressed before it is started.
- 16.2 Researchers must complete the Ethics Checklist on Worktribe, the University Research Information System, as part of the project preparation.
- 16.3 Those projects that do not have any elements of ethical risk associated with the research, do not need to seek formal approval from the Faculty Ethics Committee.
- 16.4 This includes research conducted as part of taught programmes.
- 16.5 Researchers must abide by the principles of research ethics outlined in University's Research Ethics Policy.
- 16.6 Ethical approval is not required prior to applying for research funding but must be must be gained prior to any research taking place.
- 16.7 The ethical risk level should be assigned by the project PI and confirmed by the Faculty Ethics Officer. The Faculty Ethics Officer may seek guidance from Subject Specialist Ethics Officers where required.
- 16.8 For security sensitive research projects, researchers must adhere to the University Security Sensitive Research Procedure and Policy.

17. Obtaining Approval

Undergraduate and Taught Postgraduate Students

- 17.1 Undergraduate research students are not permitted to conduct high ethical risk research.
- 17.2 Taught postgraduate students are permitted to conduct high ethical risk research appropriate to the students' experience and skills with approval from the Faculty Ethics Committee.
- 17.3 For all undergraduate and postgraduate taught research projects of low ethical risk, the ethics application must be processed and reported using Canvas to ensure a transparency of the review process.
- 17.4 All undergraduate and postgraduate taught research projects will be reviewed by two academics independent of the research project. This will be the Module Lead and the Programme Lead under which the project is conducted.
- 17.5 Undergraduate and taught postgraduate students who fail to obtain ethical approval may conduct research projects not requiring ethical review so as not to impede the course progression and completion. E.g., a literature review of non-sensitive material.
- 17.6 Either the Module Lead or Programme Lead reviewing undergraduate or taught postgraduate ethics applications must be a member of the College of Reviewers.
- 17.7 The Module Lead will report student compliance annually to the School Director of Research.

The report will include the total number of projects, the number of ethics applications approved and the number of projects not requiring approval.

- 17.8 The Faculty Research Lead will report student compliance annually to the Faculty Ethics Committee. The report will also include any incidence of adverse events involving student research misconduct.
- 17.9 Each Faculty Ethics Committee will prepare guidelines for the work of undergraduate and taught postgraduate students setting out the procedure and review mechanisms.
- 17.10 Each student and his or her academic supervisor must confirm in writing that they have read and will abide by the guidelines. Any difficulties in following the guidelines will be referred to the Faculty Ethics Committee.

Undergraduate Taught Practical Classes

- 17.11 Practical classes involving human or animal material must obtain ethical approval from the Faculty Ethics Committee. This approval can be valid for up to 5 years at the discretion of the Committee.
- 17.12 The application for a practical class demonstration, experiment or placement must include details of all procedures requiring approval.
- 17.13 All undergraduate practical classes are only permitted to involve low ethical risk procedures and will be processed via the low risk route.

Staff or Postgraduate Research Proposals

- 17.14 An application prepared by a member of staff or a postgraduate research student (applicant) must be submitted to the Faculty Ethics Committee for consideration.
- 17.15 If an application is approved by the Faculty Ethics Committee, the proposed research shall proceed.
- 17.16 If the application is rejected by the Faculty Ethics Committee, the applicant can either abandon the proposal or rethink the proposal and resubmit it to the Committee. The Faculty Research Ethics Committee must provide feedback to applicants for any decision and provide guidance on revising the application where appropriate.
- 17.17 If during its consideration of an application the Faculty Ethics Committee considers that the application entails major ethical issues, conflict of interests or high institutional risk, it may seek advice from the Special Advisory Group. The application must be accompanied by full details of the Committee's deliberations, together with observations from the Faculty Research Committee.

Research involving University of Hull Staff or Students

- 17.18 Any researchers intending to conduct research involving University staff or students must obtain ethical approval from the Faculty Ethics Committee of the PI as well as permission to conduct the research from the Faculty Dean of research subjects.
- 17.19 Researchers intending to conduct activities involving surveys of students, must obtain approval from Learning and Teaching Enhancement. Please refer to the Policy on Student Surveys for further information.
- 17.20 Researchers must obtain appropriate informed consent from participating students and staff where relevant. Advice should be sought from the Faculty Ethics Committee in cases of ambiguity.

Low Ethical Risk Projects

- 17.21 Low risk applications should be reviewed by delegated review.
- 17.22 Delegated review is a proportionate review of the application by a minimum of two reviewers electronically to reflect the risk associated with the research. These reviewers must be members of the College of Reviewers and will provide a recommendation to the Faculty Ethics Committee.
- 17.23 The reviewers must submit the review to the Faculty Ethics Officer within 10 working days.
- 17.24 If a consensus is agreed between the reviewers, the Faculty Ethics Officer will forward the recommendations to the Chair for the Chair to decide whether to uphold the recommendations. The Faculty Ethics Officer will inform the applicant of the result on behalf of the Chair together with any constructive comments from the reviewers.
- 17.25 If the review is favourable, the applicant may proceed with the research project.
- 17.26 Should an application require minor amendments, the applicant must address the concerns raised directly and resubmit for approval by Chair's Action subject to the changes.
- 17.27 If a consensus is not agreed between the reviewers, the Faculty Ethics Officer may invite a third reviewer or escalate the application to a full panel committee review with approval by the Chair.
- 17.28 The third reviewer may be the Chair of the Faculty Ethics Committee.
- 17.29 Reviewers may make contact to discuss an application if required.

High Ethical Risk Projects

- 17.30 All high ethical risk research must be scrutinized by a full panel committee review.
- 17.31 The applicant may be invited to the Committee meeting to discuss the application with the panel.
- 17.32 Should the Committee unanimously agree to recommend to approve or reject the application to the Chair and this is upheld by the Chair, the Secretary will inform the Faculty Ethics Officer.
- 17.33 Should the Committee fail to unanimously agree a recommendation, the Chair may decide to request further expert advice from members of the College of Reviewers or request to convene the Special Advisory Group.
- 17.34 The Faculty Ethics Officer will inform the applicant of the outcome of the review.

Escalation

- 17.35 An application may be escalated from low risk to high at the discretion of the Faculty Ethics Chair.
- 17.36 The Faculty Ethics Chair may seek advice and support from the Special Advisory Group for proposals with high institutional risk, at any point of the application process.

18. Post Approval

Appeals

- 18.1 Appeals and complaints against a decision should be directed to the Chair of the relevant Faculty Ethics Committee in the first instance.
- 18.2 For all student research, appeals or complaints must be made by the supervisor on behalf of the student to the Chair.
- 18.3 The Faculty Dean or Associate Dean for Research may request the Chair review a decision at

their discretion if they have concerns about the formal ethical review of proposed research within their Faculty.

- 18.4 The Faculty Ethics Committee Chair may request advice from the Special Advisory Group for appeals lodged against the decision itself.
- 18.5 Researchers may formally appeal to the University Ethics Committee to challenge the process of review of an application by the Faculty Ethics Committee. The University Ethics Committee will not review the decision made by the Faculty Ethics Committee but rather the process through which the decision was made.

Amendments

- 18.6 Amendments may be made to ethics application after the project has commenced but must be approved prior to implementing the changes in practice.
- 18.7 Minor amendments may be reviewed by the Chair and approved by Chair's Action.
- 18.8 Major amendments to an ethics application must be reviewed through the normal route ascribed to the risk.

19. Projects involving external partners

- 19.1 Researchers must register in the University Ethics Checklist on the Research Information System that the project requires approval by an external committee.

Integrated Research Applications System (IRAS)

- 19.2 IRAS applications for which the University is the sponsor, must be approved for submission by Research Governance prior to submission., Research Governance will review the application to ensure high quality and complete applications are submitted to the HRA, not a full ethical review of the proposed project.
- 19.3 Researchers must submit a copy of the recognised or authorised Faculty Research Ethics Committee approval letter for IRAS applications prior to commencing the research.

NB. Recognised and authorised RECs are ethics committees that are governed by the Governance Arrangements for Research Ethics Committees (GAfREC). These include National Health Service RECs, Social Care RECs and Ministry of Defence REC.

External review from other institutions and review boards

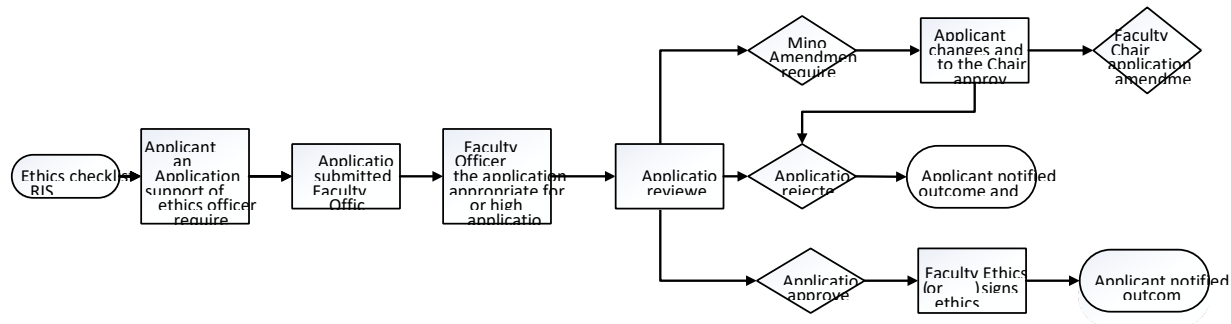
- 19.4 PIs must submit a copy of the approval letter for applications submitted to external ethics committees to the Faculty Ethics Officer for research conducted on behalf of the University on institutional and non-institutional premises.
- 19.5 For collaborative research, researchers should obtain approval from the relevant Faculty Ethics Committee for the research that is conducted on University premises where appropriate.
- 19.6 Applications to the Ministry of Defence Research Ethics Committee must be made through the Ministry of Defence application system accessed [here](#).
- 19.7 Where ethical approval is obtained from an external board, researchers must ensure that all relevant licences, permits and approvals are obtained for the activities to be conducted prior to the work commencing.

SECTION D: BREACHES OF THE POLICY

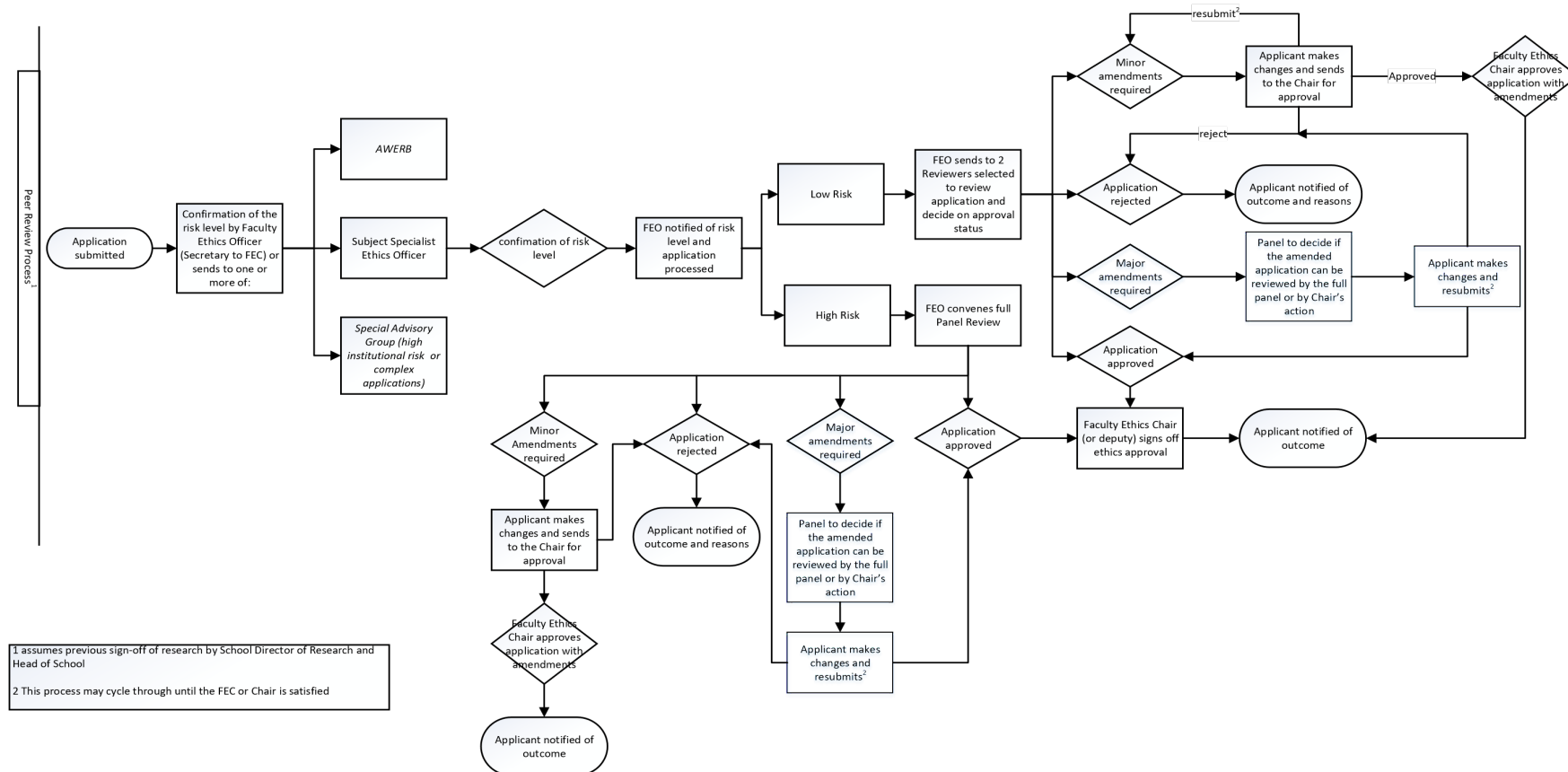
20. Breaches

- 20.1 University research staff and students that fail to adhere to this policy will be managed under the Research Misconduct Policy.
- 20.2 All members of the University are encouraged to report any concerns for breaches of this policy should contact the relevant Faculty Ethics Officer or his/her line manager following the University's *Policy and Procedure on Disclosures in the Public Interest (Whistleblowing)*.

APPENDIX 1: ETHICS APPLICATION PROCEDURE FOR STAFF AND POSTGRADUATE RESEARCH APPLICANTS



APPENDIX 2: GENERAL APPLICATION PROCESSING FOR LOW AND HIGH RISK ETHICS APPLICATIONS



Version Control

Version	Author	Date approved	Relevant sections
V1.2	Research Governance and Quality Officer	16/01/2023	Typographical errors and update to roles and contact details