UNIVERSITY OF ABERDEEN

PHYSICAL SCIENCES AND ENGINEERING ETHICS BOARD

STANDARD OPERATION PROCEDURE FOR RESEARCH ETHICS REVIEW

	Board/Committee	Date
Previously considered/approved by	PSEEB	20 th November 2023
Further consideration/approval required by	EAG	20 th November 2023

1. Abbreviations:

PSEEB - Physical Sciences and Engineering Ethics Board

REC - Research Ethics Committee

EAG - Ethics Advisory Group

RPS Team - Research Policy and Strategy Team, Research & Innovation

RGH - Research Governance Handbook

URC - University Research Committee

SEO - School Ethics Officer

2. Definitions:

The Board – the Physical Sciences and Engineering Ethics Board

Researcher – any person affiliated with the University that conducts a research project producing academic outputs. This includes amongst others staff, students, honorary members

Triage – A stage within the Worktribe ethic review process in which administrative staff (Triager) assess and process the application

3. Scope:

This Standard Operating Procedure for Research Ethics Review describes the process for ethical review as it is conducted by the Physical Sciences and Engineering Ethics Board (PSEEB). It applies to and should be read by all staff, students and associates carrying out research requiring ethical approval within the Schools of Engineering, Geosciences and Natural and Computing Sciences at the University of Aberdeen.

The Standard Operating Procedure will be reviewed once a year and must be approved by the relevant School Executive Group and the Ethics Advisory Group.

4. Purpose and Background:

Ethical review may be necessary for a variety of forms of research. It is a requirement of the University and of the majority of funding bodies that approval is sought and obtained for any research with certain defined characteristics (see University of Aberdeen Research Governance Handbook); this includes any research that involves human participants. The Physical Sciences & Engineering Board has developed a Policy for Ethical Review and Approval. This policy applies to research conducted as part of:

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- Academic-led research projects.
- Postgraduate and undergraduate research projects, including dissertation and thesis projects.

It covers research in all areas of the physical sciences and engineering and applies to staff and students from the Schools of Engineering, Geosciences and Natural and Computing Sciences. The Board also reviews and approves research projects from other areas of the University when appropriate, by arrangement with other University ethics committees.

The University of Aberdeen Research Governance Handbook (RGH) sets out the expectations for ethical review at the University and aims to provide consistent standards. The University recognises that researchers (and their supervisors where applicable) are responsible for and best placed to evaluate the ethical issues and the conduct of their research, and are accountable for the design, management and conduct of their research. Independent ethical scrutiny and review should be of sufficient quality to be useful in improving the ethical conduct of the proposed research and in ensuring that ethical standards are applied consistently. High quality and responsive ethical review will:

- Ensure that the safety, rights, dignity and welfare of all research participants are protected
- Assist researchers to develop well-designed, well-conducted and well-managed research projects which can lead to higher quality findings and outputs
- Protect researchers from the significant consequences of unethical, non-compliant or poorly conducted research
- Maintain public trust in research and in the institution. We recognise that members of the public fund
 and participate in research and consider the impact of damage to trust and reputation on the ability of
 the University to deliver this core function
- Comply with the Concordat to Support Research Integrity and provides a visible measure of standards for reporting to UKRI and other relevant bodies

It is the responsibility of the Principal Investigator, the supervisor, or the Programme Co-ordinator to ensure this policy is adhered to. Further information about the Board's ethics process can be found here.

Ethical approval should be sought as early in the research proposal process as possible and **must** be in place **before the research activity commences**. For all research projects, the applicant should complete the self-assessment as described below to determine whether further ethical review will be required. All applicants must adhere to the University's Research Ethics requirements, and for **funded research projects** this includes abiding by any further ethics principles specified by the funding body.

5. General guidance for researchers:

5.1 Responsibilities of the Researchers and Supervisors

The ethical review process has two stages. All academic research projects must be ethically assessed by the researcher to determine whether there is a need for formal ethical approval. If internal ethical approval is required, the researcher must submit an ethics application as per the application procedure (see 6). Where the application relates to a specific research project, the self-assessment and application should be made by the Principal Investigator on the project, which in some cases will be students. Supervisors are responsible for supporting their students in the process and ensuring that students abide by this Standard Operating Procedure.

5.2 Training

Completion of the University's online Research Ethics and Governance training course (available on MyAberdeen) is mandatory for all staff and PGR applicants for ethical approval. This is in addition to the online training course in Research Integrity (which is mandatory for all PGRs and researchers, and is also available on MyAberdeen). Applications will be returned to the applicant if this training has not been completed. (Completion of the training by UG and PGT students is not mandatory and will only be required at the discretion of the Course Coordinator/dissertation supervisor.)

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5.3 Considerations when applying for ethical approval

When making an application for the ethical approval of research activity, researchers should first refer to the Board's Ethics Guidance for Applicants and contact their School Ethics Officer (or deputy) for advice on completing the application. Researchers are also advised to consult the Worktribe Ethics guidance when preparing their application, as this provides further information on the associated question sets. PGR supervisors are responsible for oversight (and initial approval) of applications for ethical approval submitted by their students, hence should be the initial point of contact for their students, with further advice sought from the School Ethics Officer where necessary.

6. Application and review procedure

The procedures for staff and students to obtain ethical approval are outlined below.

6.1 Staff

The researcher must determine by self-assessment whether their planned research requires formal ethical approval, using the <u>University's Ethics Checklist</u>. If applicants are uncertain, they should contact the relevant <u>representatives of the Board</u>. Staff applications should be created and submitted using the <u>Worktribe Ethics</u> <u>Process</u>. More guidance on the process can be found under 6.4.

6.2 Postgraduate Research Students

Postgraduate Research students must determine by self-assessment whether their planned research requires formal ethical approval, using the <u>University's Ethics Checklist</u>. If applicants are uncertain, they should contact the relevant <u>representatives of the Board</u>. Postgraduate Research applications should be created and submitted by the student using the <u>Worktribe Ethics Process</u>. When creating an ethics application on Worktribe, the student will be required to indicate that the application is related to a student project, their degree, and who their supervisor is. Further guidance on the subsequent process can be found under 6.4.

6.3 Undergraduate and Postgraduate Taught Students

Undergraduate and Taught Postgraduate students are required complete ANNEX A – Ethics Checklist for UG and PGT students and, if ethics review is needed, fill out ANNEX B - Research Ethics Review Form. If human participants are involved, the Board's templates for Participant Information Sheets and Consent Forms should be used (see 6.5). The completed application form and all relevant documentation should then be submitted via the School's ethical review process – applicants should consult their supervisor and/or Programme/Project Coordinator for further details.

6.4 The Worktribe Ethics Review Process

When preparing the ethics application on Worktribe, applicants should consult the <u>current guidance</u>. In addition to the application, relevant documentation (e.g. consent forms, participant information sheet, etc) might also need to be prepared and uploaded to the application – see information on relevant documentation and templates in 6.5.

Once a staff member has submitted the online form, it will be forwarded to the triage process. Whenever a student submits the online form, the application will move into the "Submission" stage, during which the supervisor has the responsibility for confirming that the application is of an appropriate standard for submission. The supervisor can either not approve, which returns the application to the student for revisions, or approve it, moving it to the triage process.

The triage process is an administrative check for completeness of the application. If the Triager identifies that essential information or documentation is missing, the application might be returned to the applicant (usually within 48h) with comments that will need to be addressed before the application can be forwarded into formal ethics review. Applications which include all the required information and documentation for reviewers to

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evaluate the project will be passed to the Board for review. Based on the nature of the research, the Triager will assign a risk level to the application that reflects the extent of ethical consideration required, as outlined by the Risk Guidance developed by the Ethics Advisory Group. In most instances, all applications (irrespective of the associated risk level) are jointly reviewed by two School Ethics Officers, one of which would normally be from the School the application originates from. Review requests will be issued to the reviewers, and, in the first instance, a **review period of three weeks allowed**. Reviewers receive an automated reminder one week prior to the due date. In complex cases, additional review by the convener or the full Board might be required. Once reviews are marked as complete, Triage will prepare a response to the applicant based on the Board's feedback (all feedback will be anonymised).

The applicant will be informed about the Board's decision via an automated Worktribe notification e-mail. Approval for the project is indicated by the status "Favourable Opinion" and the message that "ethical approval has now been granted for [the] project to proceed". Only after receiving this outcome can the research project commence (including recruitment and data collection). The researcher must adhere to the outlined methods and project dates, and if their research plans change, they must request an amendment to the application before proceeding – see 6.6.

Alternatively, the notification might indicate that Triage requests additional information, hence amendments to the application will be necessary to meet the ethical standards expected by the Board. In the latter case, the application would return to the "Revision" status, allowing the applicant and other editors to revise and resubmit the application. The applicant must address all comments that require changes to be made to their responses within the application and/or to their supporting documentation. Where the applicant does not agree with a comment, they should indicate in the Comments tab why the reviewer's suggestions are not feasible or appropriate. Once a revised staff application is resubmitted, it moves into the triage process. If a student application is resubmitted, it moves first to the "Revision Submission" stage in which the supervisor is responsible for checking if the Board's feedback has been sufficiently addressed. The revised application must be approved by the supervisor before it will proceed to the Triage stage.

Based on the type of revisions that were required, the application can either be approved at Triage stage or will need to be reviewed again by the Board. Where possible, a joint review will be requested from the original reviewers, and a copy of their previous comments provided. In most circumstances, reviewers will be asked to complete their second (and any subsequent) reviews within one week, this however depends on the extent of the revisions requested. Once reviews are marked as complete, the Triager will prepare a response to the applicant based on the new feedback from the Board.

6.5 Required documentation for ethics applications

When involving human participants, researchers must ensure voluntary and informed participation, which is managed (in most cases) by preparing a Participant Information Sheet and a Consent Form.

In order to support researchers in providing relevant information to the participants and obtaining informed, voluntary and sufficient consent, the <u>Board provides templates</u> that include standardised text as well as sections which must be adapted to reflect the specific requirements of the project.

If semi-structured/structured interviews are planned, a document containing proposed questions should be provided alongside the application. This helps reviewers understand the type of conversation the researcher will have with the participants and the relevant ethical implications. For surveys, a copy of the questionnaire should be attached (URLs are not sufficient as they cannot be kept as permanent record).

Note: All information provided to (potential) participants that provides details of the research must be attached to the ethics application. This includes e.g. recruitment posters, de-brief sheets etc.

If researchers plan to involve vulnerable participants (e.g. those that are underage, have cognitive impairments, find themselves in a dependent or unequal relationship with the researcher), the application may also require a

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safeguarding plan to be attached. Applicants should consult the <u>Safeguarding in Research & Innovation Code</u> of Practice.

6.6 Amendment of approved applications

If staff and postgraduate student applicants require to amend their already approved application, this must be done via the amendment process within Worktribe. Amendments will be processed by the Board as per the guidance note on 'Minor/Major Amendments'. If the objectives of the project change significantly, or if collected data will be analysed within a new context that participants did not originally consent to, a new ethics application may be required. Applicants should contact the Board's convener to check if a new application is required. Postgraduate taught and undergraduate students should contact the individual who managed their application review process.

6.7 Conflict of interest within the process

To ensure a fair review, the Board will consider potential conflicts of interest when requesting reviews and approving applications. Where a School Ethics Officer is involved in a research project that requires ethical approval, they cannot review any associated ethics applications and must alert the Triager to their involvement. If reviewers identify any other conflict of interest that could impede an objective review, they must also alert the Triager. If a Triager is involved in a research project that requires ethical approval, they must not process the application.

6.8 Appeals

If staff and postgraduate student applicants wish to raise an issue with the feedback provided on their Worktribe ethics application, they should in the first instance contact the Triager to explain their concerns. The Triager will communicate this to the reviewers for their consideration. If reviewers disagree with the applicant, the Triager will refer the matter to the convener of the Board. It is expected that in most instances, agreement will be reached by a supportive dialogue between the applicant and the Board.

If all possible means of informal resolution have been exhausted and discussion with the Board fails to resolve the issue satisfactorily, an appeal may then be submitted to the University's Ethics Advisory Group via the 'Policy and Procedure on Appeals (Worktribe Ethics)'.

6.9 Record keeping

Records relating to review (applications, correspondence, review and decisions) will be kept for at least 6 years after the completion of the project (for staff projects) or for 6 years after the conclusion of the student's programme of study, or for as long as required by the project funder (where relevant).

Researchers must specify their research data retention periods within their ethics application and also in their Data Management Plan (where a data management plan is required). Where funders or publishers do not require longer retention periods, the University stipulates a minimum retention of 5 years after project end date. Researchers must retain a record of their ethics approval in case evidence of ethical approval is required beyond that date.

7. Audit and monitoring procedures, including end of project reporting

Selected research projects and REC review processes may be audited each year by the Research Policy and Strategy team. The research project audit process aims to ensure that researchers have conducted their research in accordance with the information provided within their ethics application e.g. consent forms have been retained, their research record keeping meets the required standards and their research data is being stored correctly. An audit may also be triggered as a result of a complaint or concern. Annual (selected) audits of REC decision-making and record-keeping will be carried out on behalf of the Ethics Advisory Group, reporting to the University Research Committee.

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RECs may identify projects during the review process that require additional mid-term reporting or audit. Where this is required, this will be noted as a condition of the favourable opinion and the PI notified.

8. Process for reporting adverse events and complaints

All staff, students and associates carrying out research under the auspices of the University of Aberdeen and all REC members are expected to report any complaints and adverse events or incidents that they become aware of. The report must be made to the University's Research Policy & Governance Officer (or nominated delegate during their absence) within 24 hours of occurrence or receipt, or as soon as reasonably practicable (to Dawn.Foster@abdn.ac.uk).

The Research Policy and Strategy Team will follow the University's Research Governance standard procedures on complaints and may request further information, including corrective and preventative measures already undertaken. Depending on the nature of the complaint or adverse events, immediate measures (such as the suspension of the study) may need to be implemented to protect the safety, dignity and wellbeing of participants or staff.

9. Reference Documents:

- a) University of Aberdeen Research Governance Handbook and appendices
- b) PSEEB Board Remit
- c) PSEEB SEO Best Practice Guidance and Duties
- d) PSEEB Ethics Guidance for Applicants
- e) University of Aberdeen Worktribe Ethics Approval Processes: Assigning Risk Questions and Guidance at Triage Stage
- f) University of Aberdeen Worktribe Ethics Approval Processes: Minor/Major Amendments
- g) University of Aberdeen Safeguarding in Research & Innovation Code of Practice
- h) University of Aberdeen Ethics review appeals process
- i) ANNEX A Ethics Checklist
- j) ANNEX B Research Ethics Review Form
- k) ANNEX C Participant Information Sheet Template
- I) ANNEX D Consent Form Template (Interview)
- m) ANNEX E Consent Form Template (Online)

10. Related Documents – suggested reading:

- a) UKRIO/ARMA Research Ethics Support and Review in Organisations
- b) Concordat to Support Research Integrity

Applies to	Applies to the applicants to and board members of the Physical Sciences and Engineering Ethics Board
Valid from date	20 th November 2023
Review date	Annually
Approved date	20 th November 2023
Approved by	PSEEB

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Version number	Instruction	Author	Date
1.0	First version approved	Tanja Schwanck	20 th Nov 2023

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