

**FACULTY OF EDUCATION**

**RESEARCH ETHICS COMMITTEE (REC)**

**STANDARD OPERATING PROCEDURES**

# 1. Definitions

1.1. *Consensus* means a generally accepted opinion or decision among a group of people.

1.2. *Research* means a systematic process of collecting and analysing data in order to increase the understanding of a phenomenon with which the researcher(s) are concerned or interested.

1.3. *Research participant* means a person who has consented to participate in research. For the purposes of this document, this includes animals where the research involves animals rather than humans.

*1.4. Adverse Event* (*AE*) means an event that occurs during the course of research that either causes physical or psychological harm to humans or animals, or increases the risk of physical or psychological harm to humans or animals, or results in a loss of privacy and/or confidentiality or a violation of human dignity to a research participant or others (such as family members).

*1.5. Secondary use of data* means access to and use of data for research that already exists and was collected and stored for a purpose not related to the research for which it is currently being used.

*1.6. Serious Adverse Event* (*SAE*) means an adverse event that causes, or has the potential to cause serious physical or psychological harm to a participant or animal. Seriousness of an adverse event may also relate to frequency or magnitude that is out of character compared to what is known about a related adverse event. For example, an adverse event that happens much more frequently than is expected or causes more harm than expected (in terms of what is known about the adverse event).

# 2. Research Requiring Ethical Review and Approval

2.1. In general, all research involving humans or animals, or research requiring access to private data belonging to an organisation, requires ethical clearance meaning that a research ethics application compiled according to the Faculty of Education guidelines must be submitted to the REC for review.

2.2. The above includes research for non-qualification purposes.

2.3. Routine teaching and learning or quality assurance activities not contemplated as being for the purposes of research are not included in 2.1 above. However, if there is any possibility that such activities might lead to a publication, or that publication may at some future time be desired, then prospective ethical clearance should be sought in line with 2.1. Retrospective ethical clearance will not be considered under any circumstances.

2.4. Research requiring secondary use of existing data requires prospective ethical clearance.

2.5. A waiver of the requirement for ethical review can be granted by the REC if:

2.5.1 The research is based solely on information in the public domain, legislation or regulations,

2.5.2 The proposed research is of a purely theoretical nature and does not at any point involve data derived from humans, animals, public or private organisations or

2.5.3 The research falls into another specific category defined by the Faculty and which does not involve data derived from humans, animals, public or private organisations.

2.5.4 Waivers should be applied for in the Faculty REC’s application for exemption form and granted by the REC in writing.

# 3. Application Procedures

3.1. All applications for ethical clearance are submitted electronically to the Faculty’s dedicated ethics application email address: eduethics@uj.ac.za.

3.2. A single electronic copy of the detailed Faculty Application form, with all annexures (including questionnaires or other data collection instruments) in one document.

3.3. The version must appear on the file name and cover of the research proposal/application form cover page and must be changed to revised version of the proposal where a resubmission is made.

3.4. Documents that do not have all the required signatures and dates will be returned to the supervisor and student, regardless of submission deadlines.

3.5. In order to be placed on the agenda of an REC meeting for consideration, a complete and signed research ethics application must be submitted via the email address given in 3.1 no later than the published closing date for a particular REC meeting. No late applications will be considered.

# 4. Review Procedure

4.1. Scope of Ethics Review

4.1.1. Although typically a minimum of two REC members review ethical clearance applications independently, ethics review cannot be conducted holistically without consideration of factors such as academic merit and scientific rigour.

4.1.2. Flawed research design and methods relate directly to ethics in the sense that such studies may expose participants to risk without any compensatory benefits in the form of valid knowledge as an output and the principal consideration of the REC is the protection of the interests of research participants. Exposure of participants to bad science is in itself unethical.

4.1.3. Scientific review and initial ethical screening by the Faculty Higher Degrees Committee (FHDC), or delegated structures (e.g. Departments or Doctoral Committees should always precede ethics review and only applications whose research proposals that have been approved as part of this process should be considered for ethics review (with the exception of non-qualification research which does not require FHDC approval).

4.1.4. As far as possible, ethics reviewers should not require significant revision or resubmission of research proposals based solely on factors related to research design, methodology or academic merit if the research proposal has already been approved by the FHDC or its delegated sub-committee.

4.2. The Review Process

4.2.1. Each research ethics application requiring ethical review that has been approved by the FHDC (where necessary) is placed on an agenda for the next available REC meeting.

4.2.2. For each research ethics application undergoing review, up to two reviewers with an appropriate level of academic qualification are assigned by the Chairperson or Deputy Chairperson.

4.2.3. The two reviewers are each sent, by the Secretariat, a copy of the research ethics application (including all annexures at least seven calendar days before the relevant REC meeting).

4.2.4. Reviewers independently complete the review for each of the research ethics

applications assigned to them prior to the REC meeting at which the applications will be discussed.

4.2.5. Reviewers assign a decision to each of the research ethics applications as set out in section 5.

4.2.6. At the relevant REC meeting, each reviewer gives a summary of the key findings of their review, followed by the decision that they have assigned.

4.2.7. Further steps in the review process, specifically related to the final review decision are described in section 5 below.

# 5. Decision Categories & Decision-making

5.1. Decision Categories

The following decision categories are used to indicate decisions about ethical clearance reached by reviewers.

Table 1: Approved and Minor Revision Categories

|  |  |
| --- | --- |
| Decision | Decision Criteria |
| Approved | ***Approved “as is”***  The ethics application can be accepted “as is” and no revision is required. |
| Approved subject to clarification/minor  revision to REC  Chairperson’s satisfaction. | ***Minor revision required.***    Minor revision includes:   * Minor amendments to any subsection of the ethics application as follows: * Minor amendments to information letters, consent forms or questionnaires etc. This typically is limited to improvement of language or grammar, layout or formatting, correction of typographical errors in proposal and/or related documents that will improve comprehension or readability by research participants. * Suggestions that an assessor feels may add value to the proposal from an ethical perspective, but the inclusion/exclusion of which is left to the discretion of the supervisor. |

Table 2: Major Revision and Rejected Categories

|  |  |
| --- | --- |
| Decision | Decision Criteria |
| Provisionally approved subject to clarification/major revision(s) to the satisfaction of reviewers’ or  Chairperson(s). | In this context, “major” revision generally means revision:   * That is required, not merely suggested and; * That must address problems, flaws or inconsistencies related to research ethics and that go beyond minor errors as described above.     Major revision includes:   * Revision of the aims/objectives, research design, methods or ethical considerations and/or; * Significant revision of attachments such as information letters, consent forms, questionnaires, permission letters etc. and/or; * The above could include omissions, such as required annexures that are missing. |
| Rejected | Rejected means that the proposed research as a whole is not compatible with accepted ethical standards and cannot be salvaged with major revision. Research ethics applications that are rejected cannot be resubmitted for ethical review. |

5.2. Decision-making Procedures

5.2.1. Decisions about ethical clearance of research ethics applications are made at an REC meeting.

5.2.2. A After REC reviewers have presented a summary of their key findings and decision code as described in Section 5.1, the Chairperson will enquire from the meeting whether there is consensus on the decision.

5.2.3. If there are two different decision categories from two reviewers then the meeting will be asked for consensus on the adoption of the stricter category, or alternatively whether the reviewer who gave the stricter category is willing to change it to a more lenient category after considering the reasoning of the reviewer who gave the more lenient category.

5.2.4. During discussions around achieving consensus, all members present at the REC meeting may contribute and the supervisor (if present) may be asked for clarification of facts if required, although the supervisor may not contribute to the consensus decision. Supervisors who are not REC members may be invited to REC meetings in order to provide clarification about research under discussion, if necessary.

5.2.5. If, despite prolonged deliberation, consensus cannot be achieved on a decision category then the matter is put to a vote.

5.2.6. All REC members who normally have voting rights may vote on such a decision, with the exception of the Chairperson who does not vote.

5.2.7. The decision achieving a simple majority will be recorded as the REC’s decision.

In the event of a split decision, the Chairperson will cast the deciding vote.

5.2.8. If a decision is difficult to reach consensus on, and represents an ethically complex or challenging case, the Chairperson may suggest the establishment of an *ad hoc* subcommittee to further investigate the matter and report back to the REC with a recommendation before it is put to a vote. There must be support from the Committee for this course of action, in the form of consensus or a simple majority if it is put to a vote.

# 6. Communicating a Decision and Post-review Procedures

6.1.1 The Initial Decision

6.1.2 Final research ethics application review decisions, arrived at either by consensus or voting, are recorded in REC meetings by both the Secretariat and the Chairperson.

6.1.3 After each REC meeting, the Secretariat prepares decision letters for each research ethics application on the meeting agenda with a decision.

6.1.4 Each decision letter contains the following information:

6.1.4.1 The relevant identifying and contact details (e.g. student and supervisor or researcher names, research proposal title etc.),

6.1.4.2 The decision taken (both the decision code and an explanation of what the code means),

6.1.4.3 An explanation of the next step(s) to be taken including documents that need to be completed and,

6.1.4.4 A reminder that the research may not be commenced until final ethical clearance has been obtained in writing with a clearance number.

6.1.5 If the decision is that the research ethics application is approved, then an ethical clearance letter is sent to the student and supervisor, or researcher (see section 7 below).

6.1.6 Decision letters must be sent to the student and supervisor or researcher by electronic mail within five working days of the REC meeting at which the decisions were made.

6.2 Research Ethics applications Requiring Revision (Minor Revision)

6.2.1 Research ethics applications with a minor revision decision must be revised by the student in accordance with reviewer comments.

6.2.2 It is the responsibility of the supervisor to check the revised version of the research ethics application and to ensure that all of the required revisions have been made.

6.2.3 When the supervisor is satisfied that all of the required revisions have been made, the student and supervisor must respond to each of the two reviewers’ comments and explain what changes have been made to the original version of the research ethics application. If the student and supervisor have elected to not implement a change suggested by a reviewer, then a concise reason for this should be provided.

6.2.4 The supervisor must submit the response to reviewers and a copy of the revised research ethics application (with all required signatures on the cover page, and an updated version name indicated on the cover and revisions clearly highlighted) to the Secretariat.

6.2.5 The response to reviewers and revised ethics application is checked by the REC Chairperson or a Deputy Chairperson.

6.2.6 Once the REC Chairperson or Deputy Chairperson has approved the above, the Secretariat drafts an ethical clearance letter (see section 7 below).

6.3 Research Ethics Applications Requiring Revision (Major Revision)

6.3.1 The student and supervisor’s responsibilities with regard to revision of the research ethics application, completion of required documentation and submission are the same as those described in 6.2.1-6.2.3.

6.3.2 Once the above have been received the Secretariat forwards the response to reviewers and revised research ethics application with an updated version name is indicated on the cover and revisions clearly highlighted to the reviewer(s).

6.3.3 If there is a need for further consensus decision-making, the revised ethics application is placed on a REC meeting agenda and the procedure continues as per 4.2.3-4.2.7 above.

6.3.4 If 6.3.3 does not apply, the reviewer(s) must complete review of the revised research ethics application within 10 working days.

6.3.5 Review of the revised research ethics application should be limited to assessment of the student’s compliance with the original revisions required by the reviewer.

6.3.6 Based on the conclusion reached by the reviewer(s), a new decision is indicated by the reviewer(s).

6.3.7 The documents referred to in 6.3.2 are forwarded to the Secretariat who in turn forwards the documents to the student and supervisor.

6.3.8 If the decision after review of a revised research ethics application is a minor revision, the process continues as described in section 6.2.

6.3.9 If the decision after review of a revised research ethics application is again a major revision, the process continues as described in section 6.3.

6.3.10 If the decision code after review of a revised research ethics application is approved, the Secretariat drafts an ethical clearance letter (see section 7 below).

# 7. Final Ethical Clearance

7.1. When a completed response to reviewers and a copy of the revised research ethics application are received by the Secretariat following a minor revisions decision or the research review decision was approved, an ethical clearance letter may be drafted.

7.2. Every ethical clearance letter must contain the following:

7.1.1 The relevant identifying and contact details (e.g. student and supervisor or researcher names, research proposal title etc.),

7.1.2 Confirmation that the research has final ethical clearance,

7.1.3 A unique clearance number,

7.1.4 Any applicable clearance conditions,

7.1.5 The date on which the clearance expires,

7.1.6 A short summary of the steps to be taken in the event that the research ethics application requires amendment, and

7.1.7 A short summary of the steps to be taken in order to renew ethical clearance.

7.3. Ethical clearance may be conditional. The conditions of such clearance may vary from case to case but are generally related to intermediate steps in or deliverables of the research method that are not available for review at the time the research ethics application is submitted.

7.4. Research ethics applications that aim to generate and use questionnaires or measurement tools as part of the method should be conditionally approved, with a requirement that the newly generated questionnaire or measurement tool be ethically scrutinised in order to secure final unconditional ethical clearance.

7.5. Ethical clearance letters are delivered by electronic mail to the student and supervisor or researcher.

# 8 Appeals, Referrals and Complaints

8.1.1 Any student, supervisor or researcher may appeal a decision of the REC if they believe the decision to be unfair.

8.1.2 Appeals must be submitted directly to the REC Chairperson in writing within 20 working days of the decision having been communicated.

8.1.3 On receiving an appeal, the Chairperson will convene and Chair an *ad hoc*

Appeal Committee within seven working days consisting of at least one Deputy Chairperson and two other REC members who were not the original reviewers of the research ethics application in question and who are not members of the Department in which the student is registered (or in which the research is being carried out).

8.1.4 If the Chairperson is conflicted in the appeal, then a Deputy Chairperson convenes and Chairs the Appeal Committee.

8.1.5 If necessary, REC members or non-members with specialist expertise may be co-opted to the Appeal Committee.

8.1.6 The Appeal Committee will consider the appeal, and the original review documents and attempt to reach a decision on the matter by consensus which will be to either uphold the original decision or, if there are compelling reasons, to replace the original decision with a different decision.

8.1.7 If consensus is not possible then a voting procedure is followed, similar to that described in 5.2.5 - 5.2.8.

8.1.8 The decision reached by the Appeal Committee is communicated to the student (via the supervisor) or researcher in writing.

8.1.9 If, on the conclusion of the appeal process described above, a student, supervisor or researcher still believes that the original decision or the appeal decision is unfair they may approach the Senate Research Ethics Committee (SREC) and submit an appeal.

8.2 Complaints

8.2.1 Complaints related to any aspect of REC functioning, or related to the conduct of REC members, may be made by researchers, REC members, research participants or members of the public.

8.2.2 Complaints should be directed in writing to the Chairperson of the REC, after which the Chairperson will decide on the appropriate course of action depending on the complaint.

8.2.3 If a complainant does not wish to direct a complaint to the REC Chairperson, then the complaint should be directed in writing to the Faculty’s Vice-Dean: Research and Postgraduate Studies or the Faculty’s Executive Dean or directly to the Chairperson of the SREC.

8.2.4 If a complainant does not wish to direct a complaint to any of the above, they may do so anonymously by using the University’s Ethics Hotline **0800872846**.

# 9. Renewal of Ethical Clearance

9.1 Ethical clearance is valid until the date given on the relevant ethical clearance letter.

9.2 A short progress report must be submitted to the Secretariat by no later than two weeks after the ethical clearance renewal date (indicated on the ethical clearance letter, or last ethical clearance renewal letter).

9.3 Each REC renewal application is reviewed by the Chairperson or one of the Deputy Chairpersons and a recommendation is made to either renew the ethical clearance for an appropriate further clearance period.

9.4 Possible grounds for not renewing existing ethical clearance include unapproved material deviations from research procedure, previously unreported serious adverse events and the allocation of an E7 global code in the case of qualification research.

9.5 In the case of an E7 global code, ethical clearance may be renewed on successful appeal of the E7 if the appeal is successful in the same year.

9.6 Students, supervisors or researchers are notified about their ethical clearance renewal in writing by the Secretariat.

9.7 Renewal applications and their outcomes (i.e. successful or unsuccessful) are placed on an agenda of the next available REC meeting for noting.

9.8 If no application for renewal of ethical clearance is received by, at the most four weeks after the ethical clearance renewal date, the existing ethical clearance will have expired and the position will be that any research activities conducted after this point will be done without ethical clearance.

# 10 Amendment of Research Ethics applications with clearance

10.1 General Procedures

10.1.1 Due to unforeseen circumstances, it may sometimes be necessary to amend a research ethics application with existing ethical clearance.

10.1.2 Students and supervisors or researchers faced with the prospect of research ethics application amendments must apply to the REC detailing the proposed amendments before they are implemented.

10.1.3 The research ethics proposal amendment application, with supporting documents where necessary, and a copy of the ethical clearance letter must be submitted to the Secretariat.

10.1.4 The REC Chairperson and one Deputy Chairperson review the submitted research ethics proposal amendment application and decide whether the proposed amendments are material on the basis of, among other factors, whether the proposed amendments:

10.1.4.1 Affect the research method and the probability of delivering a meaningful and valid result.

10.1.4.2 Affect the informed consent process and whether this is viable or may necessitate a process of re-consenting.

10.1.4.3 Alter the risk to benefit ratio of the research in an unfavourable way or increase the possibility of harm to participants.

10.1.4.4 Whether the proposed amendments in any way infringe on the participants right to privacy.

10.1.5 If the two reviewers achieve consensus that the proposed research ethics application amendments are material, the student and supervisor or researcher are notified of the requirement for further review of the research ethics application.

10.1.6 Otherwise, the student and supervisor or researcher are notified that there is no need for further review of the research ethics application and that they may proceed with the implementation of the amended research ethics application.

10.1.7 If the proposed research ethics application amendments are material, the research ethics application, together with a copy of the original and amended research ethics application, is allocated to the two original research ethics application reviewers if possible.

10.1.8 The two original reviewers return their reviews of the proposed research ethics application amendments to the Secretariat within five working days and indicate their decision.

10.1.9 The Chairperson assesses the two reviewers’ decisions. If the two decisions are the same, the Chairperson requests that Secretariat notify the student and supervisor or researcher of the decision. If the decisions are different, the Chairperson considers the two original reviewers’ comments and makes a final decision which is communicated by the Secretariat to the student and supervisor or researcher.

10.1.10 If the decision referred to above in Section 10.1.8 necessitates revision of the proposed amendments this is done to the satisfaction of the Chairperson, after which a final decision is communicated to the student and supervisor or researcher.

10.1.11 A new ethical clearance letter is always issued after an application for amendments to a research ethics application with ethical clearance. The new ethical clearance letter clearly indicates that the application was made, what the outcome of the application was and any new conditions of ethical approval, or other details (such as monitoring etc.).

10.1.12 If Section 10.1.7 applies, the original ethical clearance number is amended on the new ethical clearance letter by adding the following: ‘Amendment 1’. The amendment version is incremented for any future approved amendments.

10.1.13 If Section 10.1.7 does not apply, the original ethical clearance number is used on the new ethical clearance letter.

10.1.14 All amendment applications are placed on an agenda of the next available REC meeting for notification or ratification.

10.2 Qualitative Research

10.2.1 Section 10.1 above should be read with the understanding that approaches to the acceptability of research ethics application amendments differ among research approaches or paradigms (e.g. quantitative/positivist, qualitative/interpretivist/constructivist or mixed methods/pragmatic/postpositivist).

10.2.2 Whereas the emphasis in quantitative research is on the detailed description of a research method which is accepted to be final and should ideally not change, the approach to methodological adaptation in qualitative research is acknowledged to be far more fluid and evolving with progression of the research.

10.2.3 The threshold for judging materiality of amendments in quantitative research is thus accepted as being generally lower than in qualitative research.

10.2.4 However, amendments that can be argued to have ethical implications must be seen as material regardless of the research approach or paradigm.

# 11 Monitoring, Reporting, Suspension & Termination of Research

11.1 Monitoring of Research

11.1.1 The REC reserves the right to monitor any research that it has granted ethical clearance for, at any time and for any period of time until completion of the research.

11.1.2 Requirements for monitoring of research are proportional to the risk of harm to participants.

11.1.3 Research that is considered greater than low (minimal) risk may be subject to more frequent and detailed monitoring, the particulars of which are set out in the relevant ethical clearance letter.

11.2 Reporting of Adverse Events

11.2.1 Adverse events occurring during any research cleared by the REC must be reported to the Secretariat of the REC.

11.2.2 Serious adverse and related events must be reported within 48 hours of the discovery of their occurrence, while non-serious related adverse events must be reported within five working days.

11.2.3 The Chairperson, together with one or both Deputy-Chairpersons, may make immediate recommendations regarding the research methods and procedures in relation to the reporting of a serious adverse event, if this is believed to be necessary to protect the interests of participants.

11.2.4 Notwithstanding 10.2.3, all serious related adverse events must be reviewed by the REC at a meeting as close to the reporting of the adverse event as possible.

11.2.5 All adverse event reports must be submitted to the Secretariat within the time frames indicated above.

11.3 Suspension and Termination of Research

11.3.1 The REC reserves the right to withdraw ethical clearance for any research with such clearance previously granted by the REC if it is brought to the attention of the REC, and there is reasonable *prima facie* evidence, that (i) the research is non-compliant with the research ethics application that was granted ethical clearance, or the REC SOPs, and (ii) that the interests of research participants have been harmed or are at risk of harm.

11.3.2 The REC reserves the right to intervene in any research that has not yet received ethical clearance if it is brought to the attention of the REC, and there is reasonable *prima facie* evidence, that there has been interaction with human participants or animals without prospective ethical clearance where this would have been required.

11.3.3 Research referred to in sections 11.3.1 and 11.3.2 above is considered suspended, pending an inquiry into the circumstances around the alleged non-compliance.

11.3.4 The Chairperson, in consultation with one or more Deputy Chairpersons, may determine that research should be suspended, as per the definition in section 11.3.1.

11.3.5 Immediately following this determination, the Chairperson informs the relevant student and supervisor, or researcher, in writing of the suspension. This process must be completed within 24 hours.

11.3.6 Once the relevant student and supervisor, or researcher have been informed of the suspension, the relevant Head of Department and Vice-Dean: Research and Postgraduate Studies are notified.

11.3.7 The Chairperson convenes, within five working days, an inquiry into the suspension which includes representation from the research team, the REC and the Faculty’s Vice-Dean for Research and/or the Executive Dean.

11.3.8 Findings of the inquiry must be communicated to all parties as soon as they are finalised and may involve the following:

11.3.8.1 Lifting of the suspension and reinstatement of ethical clearance, or

11.3.8.2 Remedial action aimed at rectifying the non-compliance and reinstatement of ethical clearance (provided that the remedial action is complied with) or

11.3.8.3 Termination of the research.

11.3.9 In the case of Section 11.3.8.1, the REC may impose conditions on the reinstated ethical clearance, or specific monitoring and reporting requirements.

11.3.10 Students and supervisors, or researchers, have the right to appeal findings of an inquiry referred to in Section 11.3.7 by approaching the SREC.

11.3.11 Regardless of whether or not the findings of an inquiry are appealed, the SREC must be notified of the outcome of any inquiry.

# 12 Closure of Research Projects

12.1 The REC must be notified in writing of the closure of all research projects that have been granted ethical clearance, regardless of the reason.

12.2 Closure of research projects should follow final approval of the research by the Senate Higher Degrees Committee, in the case of qualification research or completion of data collection in the case of non-qualification research.

12.3 Closure of the research has no implications for future publication arising from data collected and analysed as part of the research.

# 13 Scientific Misconduct and Unprofessional Behaviour

13.1 There is a moral obligation on all REC members to be vigilant for, and report, any suspected scientific misconduct that they may become aware of at any stage of a research project.

13.2 Instances of suspected scientific misconduct should be reported to the Chairperson, or to a Head of Department, Vice-Dean: Research and Postgraduate Studies or Executive Dean. Those reporting scientific misconduct have a right to do so anonymously by using the University’s Ethics Hotline.

13.3 Once reported, instances of suspected scientific misconduct are dealt with according to the University’s policies.

13.4 There is a similar moral obligation and professional duty on all REC members to be vigilant for, and report, any suspected unprofessional behaviour that they may become aware of at any stage of a research project.

13.5 Such suspected instances should be reported as described in 13.2 – 13.3 or through reporting mechanisms made available by the relevant statutory bodies (e.g. the Health Professions Council of South Africa).

13.6 Unprofessional conduct reported internally may also be reported to the relevant statutory body by the REC.

# 14 External Requests for Faculty Student/Staff Research Participation

14.1 External requests for research participation involving students or staff in the Faculty are made through the Strategic Research Support office.

14.2 The Strategic Research Support office provides institutional gatekeeper permission for external research, subject to its own review process.

14.3 If necessary, the Strategic Research Support office may request ethical review of an external request for research. This is done on an *ad hoc* basis through communication between the Director: Strategic Research Support and the Chairperson of a REC best positioned for this purpose.

# Approved: Senate Research Ethics Committee Meeting of 27 February 2023 Approved: Senate Meeting of 16 March 2023 Approved: Faculty Research Ethics Committee Meeting of 12 May 2023