SEGi Research Ethics Committee

Standard Operating Procedure for Application of Research Ethics Approval

1. SEGi Research Ethics Committee (REC) is responsible for the ethical approval of research studies conducted by undergraduate and postgraduate students, and staff.

2. Application must be made using the prescribed form appended. The form is available from the Research and Innovation Management Centre (RIMC), in both hard and soft copy.

3. The Principal Investigator (PI, means the main person responsible for the conduct of the research, or supervisor of student's project) is responsible for the submission of the form.

4. All sections of the form must be filled up clearly, attach with additional documents where necessary to support the research study (for example, questionnaire, consent form, etc).

5. Application must be supported by the Dean or the Head of the Faculty or School.

6. The Faculty/ School Research Ethics Committee (FSREC) is responsible for pre-evaluation of application and make appropriate recommendations to the REC for ethical approval.(Wherever applicable).

7. Applications which are recommended for ethical approver by FSREC must be submitted to RIMC on or before the 8th and 22nd of every month, for REC meeting on the second and fourth week of each month, respectively. Should any of the dates fall on a weekend or public holiday, prior submission before the due date must be made (note: REC shall meet once or twice a month, depending on number of applications received). Applications submitted after the due date will be considered in the subsequent meeting.

8. Hard copy of the form must be submitted, with a soft copy to be sent via email to Ms. Shirley (shirleydavid@segi.edu.my) at RIMC.

9. RIMC shall notify all the members of the REC on the date, time, and venue of meetings, via e-mail.

10. Application form and associated documents to support the application will be sent out by RIMC in PDF format to the REC members for scrutiny before the scheduled meeting.

11. The PI must make available any additional information or documents requested by REC members to support the application for ethical approval, before or during the meeting. The PI may also be called for a presentation during the meeting.

12. All the applications received will be discussed by REC during the meeting for their consensus decision for ethical approval.

13. For application that has been approved by the REC, an approval letter will be issued to the PI within **SEVEN (7) days**, from the date of the meeting. The approval letter will be issued by RIMC and signed by the Chairperson of the REC, bearing the following details:

    a. Research title

    b. Ethics approval number

    c. Approval date

       d.   Approval validity period

14. For questionnaire studies not involving interventions on human beings or experimental animals, evaluation for ethical approval will be done by a minimum of three REC members through virtual meeting or by circulation, depending on the number of applications received.

15. For clinical research or clinical trials that involve human subjects and/ or animals, evaluation for ethical approval will be done by all the REC members. Approval time may be longer depending on the nature of the clinical studies.

16. Based on the recommendation of the FSREC, REC may approve, or disapprove a research proposal on ethical grounds. REC may also impose conditions and restrictions on research projects that have been granted ethical approval.

17. Applications which are unsuccessful in obtaining ethical approval will be sent back to PI for necessary actions, including amendments to the research proposal before resubmission to REC for reconsideration.

18. The PI is responsible to report to the REC on any major change to the project and the reason for the change. An indication should be made of ethical implications, if any, as this may require a new application for ethics approval.

19. The PI should apply to REC for extension of ethical approval should the research studies go beyond the validity period of approval.

20. REC reserves the right to terminate or suspend a research project with approval from SEGi Research Board if the researcher was found to misuse the ethical approval given, or conduct experiments beyond the period of ethical approval, or not adhering to research code-of-conduct.

Flowchart For Application of Research Ethics Approval

Start

Prior to submission, PI ensures
- Application form is completed
- Supporting documents according to the Checklist are attached
- The form has been approved by the Dean/ Head

PI submit Application Form to FSREC of Faculty/ School

FSREC pre-evaluate application form submitted

Recommended

Not recommended

make necessary corrections and resubmit

PI submit hard and soft copy of application form and related documents to RIMC before 8th and 22nd of each month for REC meeting on 2nd and 4th week of the month, respectively (submission to be made prior to the date if the date falls on weekend or public holiday)

RIMC schedule REC meeting on 2nd and 4th week of the month

RIMC send application form and documents to REC members prior to the scheduled meeting

make necessary amendments and resubmit

Outcomes

REC meeting

Approved

Not Approved

Approval Letter issue by RIMC within 7 working days from the date of meeting

End