SEGi University

SEGI RESEARCH ETHICS APPLICATION FORM

FOR OFFICE USE ONLY

DATE RECEIVED STAMP:

SUBMISSION CHECKLIST

(Ensure all boxes have been checked before submission)

No	Item	Please put in (√) where applicable			Remarks
		Yes	No	NA	
1	**Research Ethics Application Form**				
2	**Study Proposal/ Protocol**				
3	**Questionnaire**				
4	**Study Information Sheet:**				
	English				
	Bahasa Melayu				
	Chinese				
	Tamil				
	Others				
5	**Consent Form:**				
	English				
	Bahasa Melayu				
	Chinese				
	Tamil				
	Others				
6	**Sponsorship Form**				
7	**Drug Information**				

INSTRUCTIONS

INSTRUCTIONS

1. Answer every applicable question. **DO NOT** leave blanks.
2. Text boxes will expand to the size of your answers. Use a ✔ to mark the check boxes: [✔].
3. This form does not need to be printed in color. Do not submit this first page with your waiver request.
4. Submit **ONE HARD COPY** of this form (with original inked signatures) attached with all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to RIMC. Send the **SOFT COPY** via mail to shirleydavid@segi.edu.my.
5. Attach one copy of research proposal, grant or contract, protocol and investigator's brochure for clinical trials.
6. We will not accept handwritten forms, incomplete forms. Use Times New Roman 11 point to type throughout application.

The contents of this application and attachments will be kept confidential

SEGi RESEARCH ETHICS COMMITTEE APPLICATION FORM

BOX FOR COMMITTEE USE ONLY APPLICATION NO.:

Provide all the information requested. You may designate a contact person other than yourself in Section II below to handle all correspondence.

1. Research Investigators' Information

PART 1 - SECTION 1

Name of **Principal Investigator**	Title
Position	**Faculty / School**
Address	**Telephone / Extension**
E-mail	

Provide all the information requested. Only the principal investigators will be given the signatory authority in this application.

Contact Person

PART 1 - SESSION 2

Name	Title
Position	**Faculty / School**
Address	**Telephone / Extension**
E-mail	

PART 1 - SESSION 3

Title of research project

SIGNATURES:

The undersigned acknowledge that:

1. This application is an accurate and complete description of the proposed research;

2. The research will be conducted in compliance with the recommendations of, and only after approval has been received from SEGi Research Ethics Committee. The lead researcher is responsible for all aspects of this research, including: reporting any serious adverse events or problems to SEGi Research Ethics Committee, requesting prior approval from SEGi Research Ethics Committee for modifications, and requesting a continuing review and approval**.**

A. Principal Investigator/ Co-investigator (Multicenter studies) Or Project Supervisor (for student projects)	**TYPED NAME AND SIGNATURE**	**DATE**

B. The Dean, or Head of Faculty / School acknowledges that the researcher is qualified to do the research, sufficient resources will be available, and (if no external funding review has occurred) there was an internal review of scientific merit.

	TYPED NAME AND SIGNATURE	**DATE**

2. Co-Investigators

Provide all the information requested for each co-investigator. Add sheets if necessary.

PART 2 CO-INVESTIGATORS 1

Name		Title
Position	Faculty / School	
Address		Telephone / Extension
E-mail		

PART 2 CO-INVESTIGATORS 2		
Name		Title
Position	Faculty / School	
Address		Telephone / Extension
E-mail		

PART 2 CO-INVESTIGATORS 3		
Name		Title
Position	Faculty / School	
Address		Telephone / Extension
E-mail		

PART 2 CO-INVESTIGATORS 4		
Name		Title
Position	Faculty / School	
Address		Telephone / Extension
E-mail		

3. Summary of the study

Section 1: Background and Purpose

PART 3 - SECTION 1	
	3.1.1. Provide relevant background information and explain **in layman language** why this research is important and what question(s) or hypotheses this activity is designed to answer
	describe here

3.1.2 Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, timeline for data collection, name of the test/procedure. Provide this information for each phase of the study (pilot, screening, intervention and follow-up), **Use layman language** Also include here the sample size, flow chart and Gantt chart if not included in the proposal	
describe here	
3.1.3 How many subjects will you need to **complete** this study?	
Number ___ Age range	
3.1.4 What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)	
describe here	
3.1.5 What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)	
describe here	
3.1.6 Will you give subjects gifts, payments, services without charge, or extra course credit?	
[ ]	NO
[ ]	YES, If yes, please explain.
3.1.7 Will any of the subjects or their third-party payers be charged for any study procedures?	
[ ]	NO
[ ]	YES, If yes, please explain.

3.1.8 Where will the study procedures be carried out?

3.1.9 Indicate how you will provide the subjects with the required consent-related information about the research.

Select all that apply

[ ]	An oral explanation of the research. *Examples: person-to-person, tape recording, or video recording*
[ ]	A written Information Sheet. *Examples: paper: in-person, faxed, mailed or electronic: email, website or webpage, text message, other*
[ ]	Other, describe below:

Section 2: Risk and Benefits

PART 3 -SECTION 2

3.2.1. Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

3.2.2 Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors, fetuses in uterus, prisoners, pregnant women, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group.

3.2.3 Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

3.2.4 Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

4. Adverse events

PART 4	4.1 Who will handle adverse events if any?	
	[ ]	Investigator
	[ ]	Others
	4.2 Who will be financially responsible for treatment of **physical injuries** resulting from study procedures?	
	[ ]	Study sponsor
	[ ]	Subject or subject's insurer
	[ ]	Other, explain

5. Confidentiality of Research Data

PART 5	5.1 Will you record any direct subject identifiers (names, identity card numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ?	
	[ ]	No
	[ ]	Yes. If yes, explain why this is necessary
	5.2 Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future?	
	[ ]	No
	[ ]	Yes. If yes, explain and include this in the consent form

6. Consent forms

Attach copies of all consent forms for each subject group. Include a footer identifying the version date of each form and a header or title that identifies each different form

PART 6	6.1. Indicate how you will provide the subjects with the required consent-related information about the research. *Select all that apply*	
	[ ]	An oral explanation of the research. *Examples: person-to-person, tape recording, or video recording*
	[ ]	A written Information Sheet. *Examples: paper: in-person, faxed, mailed or electronic: email, website or webpage, text message, other*

[ ] Parental permission *Attach copies of any written materials or scripts you will use with parents, to obtain their permission to enroll their minor children in your research.*

[ ] Other, describe below:

7. Drugs, Substances or Devices

PART 7 - SESSION 1

7.1. List **all** non-investigational drugs or other substances used to conduct this research (analgesics, anesthetics, drugs used to treat side effects, etc.). Include products used for standard clinical care if they are used in this study for research purposes

Name	Source	Dose	How administered

PART 7 - SESSION 2

7.2. List **all** investigational new drugs or other investigational substances to be used in the study. Include marketed products used "off-label" (different formulation, dose, route of administration, or indication). Provide:

- **three** copies of a concise summary of information about the drug prepared by the investigator (including animal and human toxicity data, studies done in animals and humans to date);
- **one** copy of the Investigator's Brochure;
- **one** copy of the study protocol.

Name	Source	Dose	How administered	IND Number	Phase of testing

PART 7 - SESSION 3	7.3. List all investigational devices you will use. Provide the information requested below and attach one copy of the company protocol. If there is no Investigational Device Exemption (IDE), explain why. Include a statement as to why the device qualifies as non-significant risk. Provide a copy of the FDA letter(s) which states the device classification (PMA, 510K, Class I, II, or II, or custom device) and categorization (Category A or B). a. Name of the device: b. Name of the manufacturer: c. Description of its purpose and how you will use it in this study: d. Descriptions of previous studies in humans and animals: e. Investigational Device Exemption

8. Recommendation for Ethics Approval by Faculty/ School Research Ethics Committee

PART 8	The Faculty/ School Research Ethics Committee has evaluated the research proposal for Ethics Approval by SEGi Research Ethics Committee. Recommended: Not Recommended: Comments (if any):	
	Chairperson	**NAME AND SIGNATURE** **DATE**

9. Recommendation for Ethics Approval by SEGi Research Ethics Committee

PART 9	The SEGi Research Ethics Committee has evaluated the research proposal for Ethics Approval. Approved: Not Approved: Comments (if any):		
	Chairperson	**NAME AND SIGNATURE**	**DATE**