THE MEDICAL RESEARCH ETHICS

INTRODUCTION

The Medical Research Ethics Committee or known as Jawatankuasa Etika Penyelidikan Perubatan is the Ethics Committee under Faculty of Medicine and Health Sciences (FMHS)

COMMITTEE DUTIES

- To discuss and approve the ethical issue of a research proposal that uses the patient as a sample of the study, especially those involving clinical trials.
- To provide advice to modify the proposed research that violates ethics.
- To terminate any ongoing or ongoing experiments that violate ethics.
- To discuss any appeal rejected applications or terminated projects.
- To provide rules and mechanisms for monitoring all research related to medical ethics.

GUIDELINES FOR APPROVAL OF MEDICAL RESEARCH ETHICS

- Any clinical research that uses human life as a subject by UMS researchers should obtain the consent of this committee.
- Research involving human waste, cadaver, tissue, biological fluid, embryo or fetus should also be approved by this committee.
- The researcher must submit an application for ethical approval to the Secretariat of the Ethics Committee using the form provided. Applications can be developed throughout the year.
- All applications will be brought to UMS Medical Research Ethics Committee Meeting for approval.
- Any research having ethical issues cannot be instituted prior to the approval of this committee. This meeting will be held 4 to 6 times a year, subject to acceptance of the application.
- Approved applications will be given the ethical approval number.

Contact us:

Science Management Sector.
1st Floor, Block E,
Faculty of Medicine and Health Sciences.
Universiti Malaysia Sabah.
Tel: 088-320000

Mr. Johan Alexander (isaac@ums.edu.my)
Mdm. Arsiyma Binti Abdul (arsiyma@ums.edu.my)
Mdm. Jainuh Anda (jainuh@ums.edu.my)

CHECKLIST FOR SUBMISSION OF MEDICAL ETHICS COMMITTEE

No	Document	Check (√)
1.	**Cover Letter** Heading: **MEDICAL ETHICS APPLICATION FOR REVIEW AND APPROVAL** *[addressed to Dean of Faculty of Medicine and Health Sciences (Ethics Committee Chairperson)]*	
2.	**Application form for Research Ethics approval** *(Please attached together all related forms/appendix, e.g. questionnaire, NMRR approval)*	
3.	**Subject Information Sheet (English and Malay versions)** *Refer to the format*	
4.	**Informed Consent Form (English and Malay versions)** *Refer to the format*	

APPLICATION FOR RESEARCH ETHICS APPROVAL

(Medical Research Ethics Committee Universiti Malaysia Sabah)

APPLICANT INFORMATION			
1.	**Name of Applicant:**		
2.	**Faculty/Institute/Center/Department:**		
3.	**Mobile No.: ……** **Office No.: …… Ext: ……** **Email: ……..**		
RESEARCH INFORMATION			
4.	**Research Title:**		
5.	**Executive Summary:**		
6.	**Research Questions, Hypotheses and Objectives:** **i)** **ii)** **iii)**		
7.	**Duration of research: _____ months /_____ years**		
8.	**Location of research/sampling:**		
9.	**Research in brief:-** **a. Human Subject Involvement:** *(Tick appropriate √)*		
	1	Questionnaires / Interviews *(please attached the questionnaire)*	
	2	Physiological Measurements	
	3	Clinical Trials of drugs / formulations	
	4	Clinical Trials of devices	
	5	Use of Human tissue samples	
	6	Use of Body fluids (e.g. blood, urine, sputum, stool)	
	7	Human genetic research	
	8	Others (please specify: .....)	

	b. Sample size:
	c. Study procedure: ***(point form)*** • ….. • …..
	d. Inclusion Criteria:
	e. Exclusion Criteria:
	f. Study population:
10.	**Other investigators involved/supervisor:** *[Please list Name /Designation /Organization]* **i)** **ii)** **iii)**
11.	**Biological Samples involved:** • **Blood/Sputum/Stool/Urine/etc:_____** • **Amount: _____**
12.	**Side Effects and Risks:** *There are neither severe side effects nor harmful risks to the subjects ……*
13.	**Storage of Data:** *(How/where/safety precaution/etc)*
14.	**Confidentiality and Ethical Conduct:** • *Participants will not be coercered to participate or give information….* • *Participants will participate voluntarily and be give informed consent forms ….* • *Participants may withdraw from the study at any time….* • *All efforts will be made by the researcher to minimise deception, respect privacy and not harm participants….* • *Participants real names will not be published in any material related to the study…* • *The data collected from the participants will be kept confidential……* • *Social and cultural sensitivity will be maintained throughout this study….*
15.	**References** 1. 2.
16.	**Please state the ethics issues that needs approval from the committee.** **1. ……** **2. ……** **3. …..**
17.	**Is your research have gone through the "screening" process in your faculty/ institute/ center/ department?** *(Please tick √)* ☐ Yes ☐ No Details/Remarks: …….

Helaian Maklumat Subjek

Kod Penyelidikan :

(Kod kelulusan geran penyelidikan [sekiranya ada])

Tajuk:

Tajuk projek

Nama dan alamat Penyelidik Utama:-

NAMA SUBJEK: ……..

PENGENALAN

Anda dijemput untuk menyertai satu kajian bertajuk "….".

TUJUAN KAJIAN

Tujuan kajian ini adalah untuk mengkaji …….

PROSEDUR PENYELIDIKAN

Jika anda bersetuju untuk mengambil bahagian dalam kajian ini, anda perlu menyediakan perkara yang berikut: ……

KESAN SAMPINGAN DAN RISIKO:

Kajian ini tidak mendatangkan apa-apa kesan sampingan yang teruk mahupun risiko-risiko yang berbahaya kepada anda…….

FAEDAH

Sekiranya anda menyertai kajian dan memenuhi keperluan…..

PENGLIBATAN DALAM KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela dan tiada paksaan. Anda mungkin boleh diminta untuk memberikan spesimen kali yang kedua sekiranya, kuantiti sampel yang pertama tidak mencukupi atau kualiti sampel pertama tidak sesuai digunakan untuk analisis atau untuk mengesahkan keputusan analisis makmal sampel pertama anda. Anda boleh memilih untuk menamatkan penglibatan dalam kajian ini pada bila-bila masa, dan ini tidak akan menjejaskan proses rawatan perubatan anda. Doktor anda akan meneruskan rawatan terhadap anda seperti biasa…….

Setelah bersetuju untuk menyertai kajian dan telah menandatangani maklumat borang kebenaran, anda boleh menarik diri pada bila-bila masa dan ini tidak akan menjejaskan rawatan akan datang dari doktor anda dan tidak akan mengakibatkan sebarang tindakan penalti…….

Anda tidak perlu memberikan sebab apabila menarik diri. Bagaimanapun , anda perlu memaklumkan kepada doktor anda atau penyelidik utama sekiranya anda menarik diri daripada kajian itu supaya spesimen fekal anda tidak akan digunakan untuk tujuan penyelidikan……

PERTANYAAN

Jika anda mempunyai sebarang soalan berkenaan kajian ini, sila hubungi penyelidik utama…..

KOS KAJIAN

Penyertaan anda dalam kajian ini adalah secara sukarela…….

Semua keputusan kajian ini akan dijaga kerahsiaannya mengikut had-had yang dibenarkan oleh undang-undang. Hasil kajian ini akan dianalisis sebagai sekumpulan data dan sekiranya perlu, akan diberikan kepada Universiti Malaysia Sabah bagi tujuan penyelidikan dan boleh diterbitkan atau diberikan kepada jabatan-jabatan yang berkenaan di Malaysia……

Sekiranya terdapat keperluan, wakil Jawatankuasa Etika boleh mendapatkan rekod perubatan anda untuk mengesahkan maklumat yang diperolehi dalam kajian. Dalam keadaan sedemikian, tahap kerahsiaan akan dikekalkan sepanjang masa. Maklumat ini tidak akan digunakan untuk tujuan lain atau didedahkan kepada pihak lain tanpa kebenaran anda……

MENGAMBIL BAHAGIAN DALAM KAJIAN

Jika anda bersetuju untuk menyertai kajian ini, anda akan diminta untuk menandatangani satu Borang Persetujuan yang menyatakan anda telah dimaklumkan tentang kajian ini, memahami sepenuhnya penjelasan daripada doktor atau penyelidik dan bersetuju untuk menyertai secara sukarela. Dengan menandatangani borang persetujuan, anda tidak mengubah hak anda. Sebelum mengambil apa-apa keputusan, anda boleh membincangkan perkara ini dengan keluarga atau kawan atau dengan doktor anda. Satu salinan borang persetujuan akan diberikan kepada anda sebagai rujukan…….

BORANG PERSETUJUAN PESERTA

"*Tajuk projek*"	**Nombor subjek :** _____

Perakuan subjek:

Dengan menandatangani Borang Persetujuan Peserta ini, saya mengesahkan perkara-perkara berikut:

☐ Saya telah membaca dan memahami Borang Persetujuan tentang kajian ini dan telah diberikan peluang untuk bertanyakan seberang soalan.

☐ Saya mengesahkan bahawa saya telah diberikan cukup masa untuk berfikir dan bersetuju untuk mengambil bahagian dalam kajian ini secara rela hati.

☐ Saya memahami sekiranya pada bila-bila masa saya memerlukan maklumat lanjut, saya boleh memintanya dari doktor atau penyelidik tersebut serta memohon untuk berhenti dari terlibat dalam kajian ini.

☐ Saya juga tahu bahawa saya tidak perlu memberi sebarang alasan sekiranya tidak ingin meneruskan penglibatan dalam kajian ini. Namun, saya akan memaklumkan kepada doktor atau penyelidik mengenai penarikan diri tersebut.

☐ Saya bersetuju sebarang penerbitan yang diterbitkan seharusnya tidak mendedahkan nama saya atau mana-mana maklumat yang dapat mengenalpasyi saya.

☐ Saya telah diberi nombor telefon doktor atau penyelidik yang boleh digunakan sekiranya terdapat sebarang pertanyaan mengenai mana-mana aspek kajian ini.

☐ Saya telah menerima satu salinan "Borang Maklumat" dan "Borang Persetujuan Peserta" untuk simpanan saya

☐ Saya bersetuju untuk terlibat dalam kajian ini dengan rela hati tanpa paksaan dan akan mengikut arahan yang diberikan.

Nama Peserta: _____ **Nombor I/C:** _____

Tandatangan Peserta: _____ **Tarikh:**_____

Nombor telefon Peserta:_____

Pengesahan dari Doktor / Penyelidik Utama:

Saya mengesahkan bahawa saya telah menerangkan tentang kemungkinan risiko kajian ini dalam isitilah yang mudah difahami oleh subjek.

Nama Doktor yang menjalankan perbincangan kebenaran subjek

: _____

No. IC : _____

Tandatangan Doktor :_____ Date: _____

Nombor telefon Doktor / Penyelidikan Utama : _____

Pengesahan dari saksi berkecuali (sekiranya perlu):

Saya dengan ini mengesahkan perkara-perkara berikut:

- Informasi mengenai keizinan mengikuti kajian ini telah diterangkan dengan jelas.
- Peserta telah diberikan peluang untuk bertanyakan sebarang soalan tentang kajian ini.
- Peserta telah bersetuju untuk terlibat dalam kajian ini dengan rela hati.

Nama Saksi: _____

No. I/C: _____

Tandatangan Saksi : _____ Tarikh: _____

No. Telefon Saksi : _____

Subject Information Sheet

Research Code:

(Approval research grant code [if any])

Title:

(Project Title)

Investigator name and address:-

SUBJECT'S NAME: ……..

INTRODUCTION
You are invited to participate in a study about…

STUDY PURPOSE
The aim of this study is to…..

RESEARCH PROCEDURE:
If you agree to take part in this study, you will have to do the following: …….

SIDE EFFECT AND RISK:
If you participate in this study, there are neither severe side effects nor harmful risks happen to you. You may feel a little bit of pain during the blood taking….

BENEFITS
If you participate and fulfill the requirement…

PARTICIPATION OF THE STUDY
Your participation in this study is voluntary and it is entirely your decision. You may be called or requested for second time of blood taking if the amount of the initial blood sample is inadequate or the quality of the first sample is not appropriate to be used for analysis or to confirm laboratory findings of your first blood sample. You can choose to leave the study at any time. If you choose not to participate, it will not affect your medical care. Your doctor will continue to treat you in his or her usual way……..

Having agreed to participate and having signed the inform consent form, if you change your mind, your choice will be respected and it will not affect any future treatment from your doctor and will result in no penalty…….

You do not have to give reason to withdraw. However, you should inform your doctor or the investigator if you withdraw from the study so that your blood will not be used for research purposes…….

ENQUIRY
If you have any questions with regards to the study, please feel free to call…….

COST OF THE STUDY
You participation in this study is voluntary…….

CONFIDENTIALITY
All the results of this study will be treated in complete confidentiality to the extent permitted by law. The yield of this study shall be analyzed as a group of data and shall be given to Universiti Malaysia Sabah for research purpose if necessary and may be published or given to regulatory authorities of Malaysia……..

It may also be necessary for Ethics Committee representatives to have access to your medical records to verify the information collected for the study. In such circumstances, confidentiality will be maintained at all times. They will not be used for any other purposes or be disclosed to any other parties without permission……..

TAKING PART IN THE STUDY

If you have agreed to participate in this study, you will be asked to sign an Informed Consent Form containing a statement to the effect that you have been informed about the research, have full understood the doctor's or investigator's explanation and voluntarily agree to take part. By signing the Informed Consent Form, you do not alter your legal rights. Before deciding to take part in this study, you may wish to discuss the matter with a relative or friend or with your local doctor. A copy of the Informed Consent Form will be given to you for your reference……..

INFORMED CONSENT FORM

(Project Title)	**Subject no :** _____

Certification by Subject:

By signing the Informed Consent Form, I confirm the following:

☐ I have read and understand the Subject Information Sheet about this study and have been given a chance to ask any questions.

☐ I confirm that I have been given enough time to think about and have freely agreed to take part in this study.

☐ I know that at any time, I can ask for more information from the doctor or the investigator and cease to participate in this study.

☐ I also understand that should I decide to stop taking part in this study, I do not need to give any reason. However, I shall inform the doctor or the investigator about my withdrawal.

☐ I agree that any publication shall not reveal my name or any other personally identification information.

☐ I have been given contact numbers from researchers for enquiries on all aspects of the study.

☐ I have received a copy of “Subject Information Form” and “Informed Consent Form” for me to keep.

☐ I agree to participate in this study voluntarily and closely follow the instructions I am given.

Subject’s Name: _____I/C No: _____

Subject’s Signature: _____ Date: _____

Subject’s Contact No:_____

Certification by Study Doctor:

I confirm that I have disclosed the risks that may be involved in this study in terms readily understood by the subject.

Name of Study Doctor Conducting the informed consent discussion:

: _____

I/C No_____

Signature of Doctor: _____ **Date:** _____

Doctor's Contact No: _____

Certification by Impartial Witness (If Applicable):

Complete this section only if an impartial witness was involved in the informed consent procedure:

I hereby confirm witness of the following:

- The information of informed consent was clearly explained to the subject.
- The subject had the opportunity to ask the questions about the trial.
- The subject had consented freely to participate in the trial.

Name of impartial witness: _____

I/C No: _____

Signature of impartial witness: _____

Date: _____

Witness's Contact No: _____