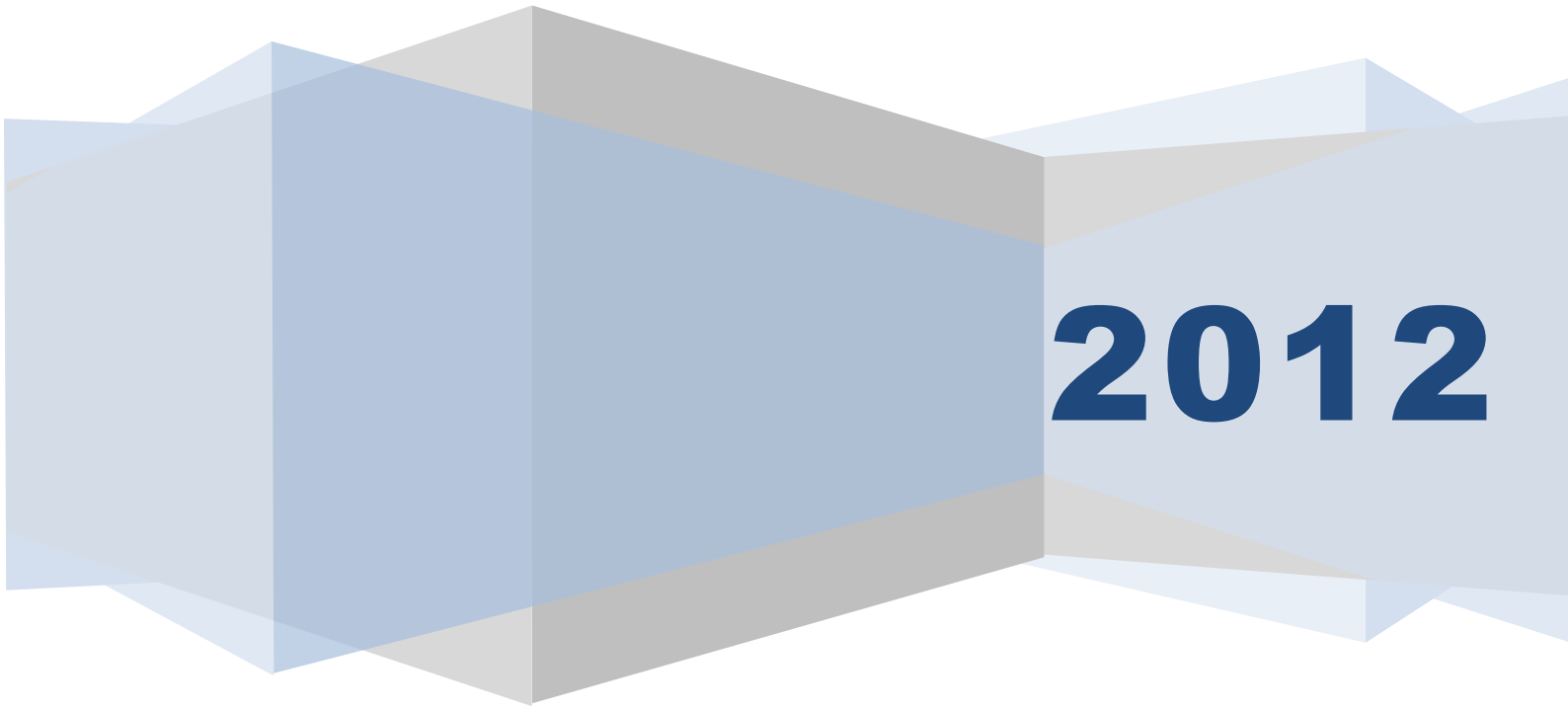
UniSZA Human Research Ethic Committee (UHREC)

SOP



UniSZA HUMAN RESEARCH ETHICS COMMITTEE (UHREC)

1.0 INTRODUCTION

In 19th October 2005, the General Conference of UNESCO adopted acclamation of Universal Declaration on Bioethics and Human Rights. For the first time in history of bioethics, Member States including Malaysia and the international community apply the fundamental principles of bioethics set forth by UNESCO. In dealing with ethical issues raised in medicine, life sciences and associated technologies as applied to human beings, the Declaration, as reflected in its title, anchors the principles it endorses in the rules that govern respect for human dignity, human rights and fundamental freedom. By enshrining bioethics in international human rights and by ensuring respect for the life of human beings, the Declaration recognizes the interrelation between ethics and human rights in the specific field of bioethics. Together with the Declaration, the General Conference of UNESCO adopted a resolution which calls upon Member States to make every effort to give effect to the principles set out in the Declaration and invites members to take appropriate steps to ensure the follow-up to the Declaration, including its widest possible dissemination.

Therefore, it is proposed that the **UniSZA Human Research Ethics Committee (UHREC)** should set out the obligations for all University researchers, staff and students to be aware of the ethical framework governing research in the University and to comply with institutional and regulatory requirements.

2.0 THE ROLE OF UniSZA HUMAN RESEARCH ETHICS COMMITTEE (UHREC)

Universiti Sultan Zainal Abidin (UniSZA) aims to promote ethical research in the university. UniSZA Human Research Ethics Committee (UHREC) is responsible to the Vice-Chancellor to ensure that all researchers whose work involves human participants will conduct their work with appropriate regards to ethical and cultural values. These principles and values include justice, safety, truthfulness, confidentiality and respect to participants of the research project. Researchers must also take into account the evolving understandings of how these principles and values are expressed in the society at a particular time. The purpose of the research is to produce evolving understanding and information which may improve the livelihood of human beings. All research involving human participants should be conducted in accordance with ethical norms and be subjected to ethical appraisal and approval of UHREC. All such research must be sensitive to the needs and characteristics of the participants. Researchers must recognize the power of relationships involved in their work particularly where there are disparities related to age, race, culture, status, religion, class, gender or sexuality between researchers and participants, or where the persons involved belong to vulnerable groups in research such as young children, or people with mental illness or socially disadvantaged. In conclusion, the role of UHREC is to provide protection for all participants in the research activity including the researchers themselves. UHREC must ensure that all researchers are aware of and seek guidance about the principles and values of ethical research involving human participants. All research:

i. has the informed consent of participants.
ii. guarantees confidentiality of data and individuals.
iii. avoids unnecessary deception and complications.
iv. minimizes risk to all participants.

3.0 TERMS OF REFERENCE

3.1 The terms of reference of the UHREC include the evaluation of the:

i. needs and worth of the research.
ii. validity of the design, procedures and methodology to be adopted, as they might have impact on any ethical or legal considerations.
iii. protection of human rights and cultural values of the participants, including the acquirement of informed consent and recognition of participants' rights to decline.
iv. ownership and use of findings and the procedures to protect personal and confidential information.
v. legal issues which might arises.
vi. procedures for effective monitoring of research.
vii. low risk project is defined as no intervention to human participants for example giving drugs, diet regimes and or body fluid sampling.
viii. respondents who are free from affiliation to other institutions.
ix. maintenance of record of all research protocols received and reviewed.
x. conduct of research approved by the Committee is appropriately monitored.
xi. others, other than as specified in these Terms of Reference, the Committee may determine its own procedures and establish its own *ad hoc* committees and working parties as necessary.

3.1.1 Chair and Deputy Chair

The Chair will be appointed by the Vice-Chancellor based on the recommendations by the Research Management Centre/Board (term as determined by the Centre/Board)

The Chairperson must be present at all meeting and no representation is allowed.

A Deputy Chairperson shall be elected by the Committee at the first meeting each year.

Indemnity

The University shall indemnify and keep indemnified each member of the Committee against all actions, suits, claims and demands whatsoever (whether arising during or after the term of office of that member) in respect of any act or thing done by that member in good faith in the exercise or purported exercise of any power or duty conferred or imposed upon the Committee or upon any member by the University.

Meetings

The Committee shall meet at least six (6) times/year
For the purposes of a meeting the quorum will be 50% of the membership with the proviso that when there is less than full attendance at the meeting.
Before the meeting commences the Chairperson must be satisfied that members have received all papers and have had an opportunity to contribute their views and that these have been recorded and considered.

Reporting

The minutes of Committee meetings will be tabled for discussion and/ or action at the subsequent meeting of the Academic Board/ Research Management Centre.

3.2 The **UHREC** will accept project applications for review only from:

i. academic staff of UniSZA
ii. visiting academic staff of UniSZA
iii. research associates (endorsed by an academic staff of UniSZA)
iv. undergraduate and postgraduate students of UniSZA
v. projects involving free respondents (e.g. healthy volunteers, immigrants etc)

3.3 **UHREC** should be multidisciplinary, multisectoral and pluralistic.

3.4 The number of members in the committee will be a minimum of seven (7) and a maximum of fifteen (15) people (see Appendix A). The committee should include at least one member who is not affiliated to UniSZA. The suggested composition of **UHREC** is as follows:

i. Two (2) to three (3) persons with expertise in basic medical sciences, including statistics.
ii. Two (2) to three (3) clinicians.
iii. A person with knowledge of ethics of medical research.
iv. A person with expertise in law.
v. A person with expertise in religion/ philosophy/social sciences.
vi. A person with expertise in public health research/biostatistics.
vii. A lay person conversant with social values.

4.0 GENERAL GUIDELINES

4.1 Members of the UniSZA Human Research Ethics Committee(UHREC)

See appendix A

4.1.1 Non- UniSZA Members

An amount of RM400 (Four Hundred Ringgit) will paid to non- UniSZA UHREC members when they come for the meeting.

4.2 Types of research that involves the use of humans as participants

Any research projects at postgraduate and undergraduate levels that involve direct contact with humans as participants will require University ethical approval (see Appendix B for a sample of a study protocol). Examples of research studies include certain types of:

i. clinical trials.
ii. observational studies.
iii. surveys.
iv. interviews.
v. audio/video taping.
vi. administration of tests or stimuli.
vii. collection or use of human tissues, bone, blood, hair, nail and other body fluids

4.3 Application for ethical approval

All research projects, conducted by staff, postgraduate and undergraduate students in UniSZA that involve human participation must have ethical clearance from the Scientific Committee of the respective faculty for minimal risk research or approval from UHREC for higher risk research. The Scientific Committee of the faculty will review project applications within one (1) week of receipt of applications, provides all necessary information and appropriate approval obtained. Medium to high risk projects must be vetted at faculty level first before submission to UHREC for final approval. (See 4.6 for documentations).

4.3.1 Other Ethical Approval

For research project involving respondents from institutions which have their own ethics committee (e.g. Ministry of Health, Pusat Perubatan Universiti Kebangsaan Malaysia), the researchers are required to seek approval from these institutions themselves. Therefore ethical approval from UHREC is no longer applicable.

4.4 Exception for low risk project

For low risk postgraduate and undergraduate projects, approval can be given by the Scientific Committee of the respective faculty. It is important that approval is granted before commencement of the research project (see Appendix C). The respective faculty vetted the research application and the faculty submit to UHREC before UHREC Review Board meeting dateline.

4.5 Members of FPSK Scientific Committee (an example of members of Scientific Committee of a faculty)

1. Deputy Dean –Research & Postgraduate.
2. Head of Centre (Clinical & Quality of Life Studies).
3. Representative from MBBS.(Clinician)
4. Representative from Medical Laboratory Technology & Biomedical Sciences.
5. Representative from Radiography and Nuclear Medicine.
6. Representative from Nutrition and Dietetics.
7. Representative from Nursing Sciences.
8. Representative from Physiotherapy.

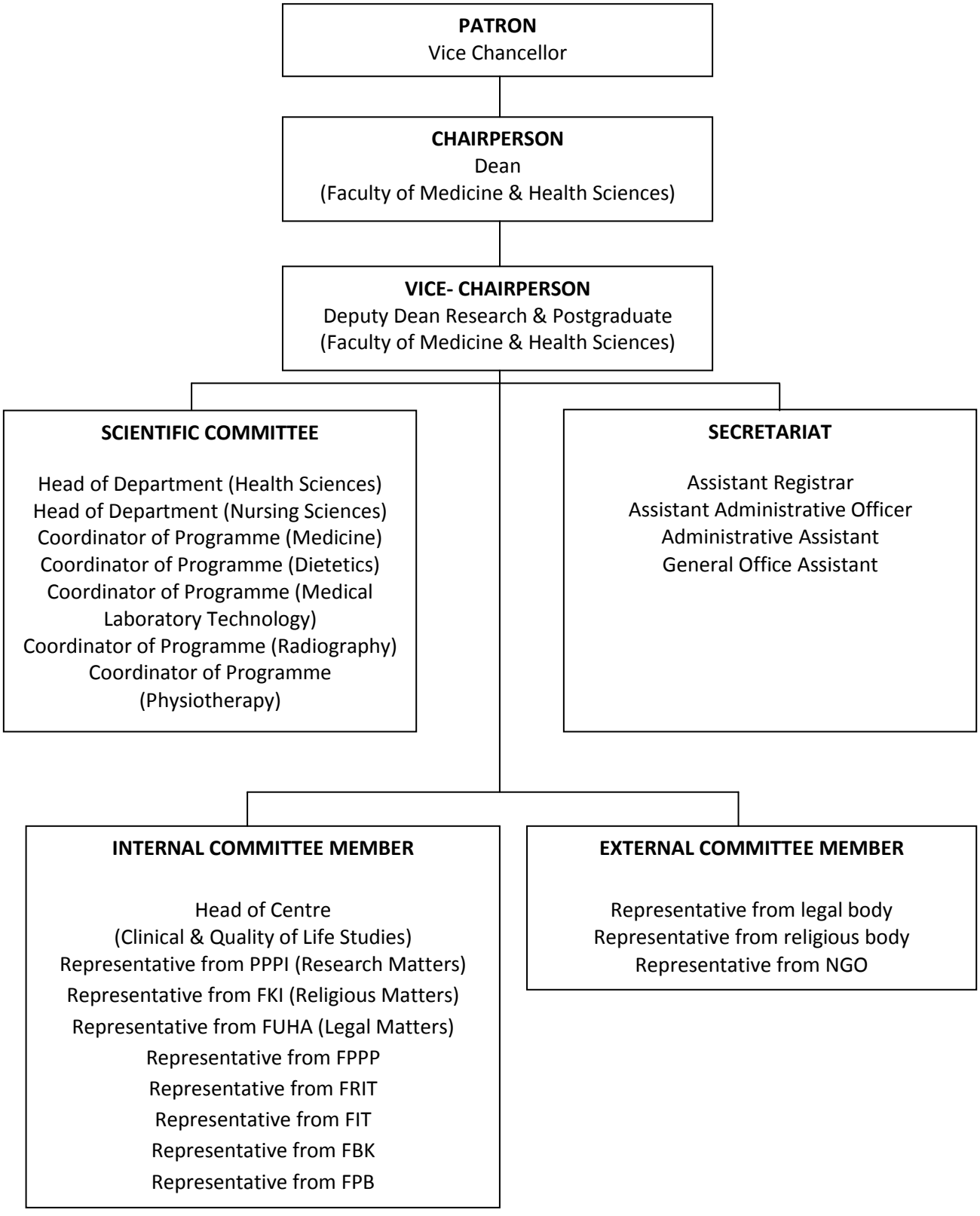
4.6 Documents and forms

All application for UHREC approval must include:

a) Standard Operating Procedure UHREC (Appendix B)
b) A completed application form for ethical Review Board UHREC (Appendix C)
c) 2 pages of curriculum vitae
d) Research grant application form(UniSZA seed grant, FRGS, LRGS, MOSTI, WHO and etc)
e) A sample of Study Protocol of Research Project (Appendix D)
f) Consent form for the research (Appendix E)
g) UHREC Meeting Schedule (Appendix F)
h) UHREC Screening Form (Appendix G)
i) Approval letter from Chairman of UHREC (Appendix H)

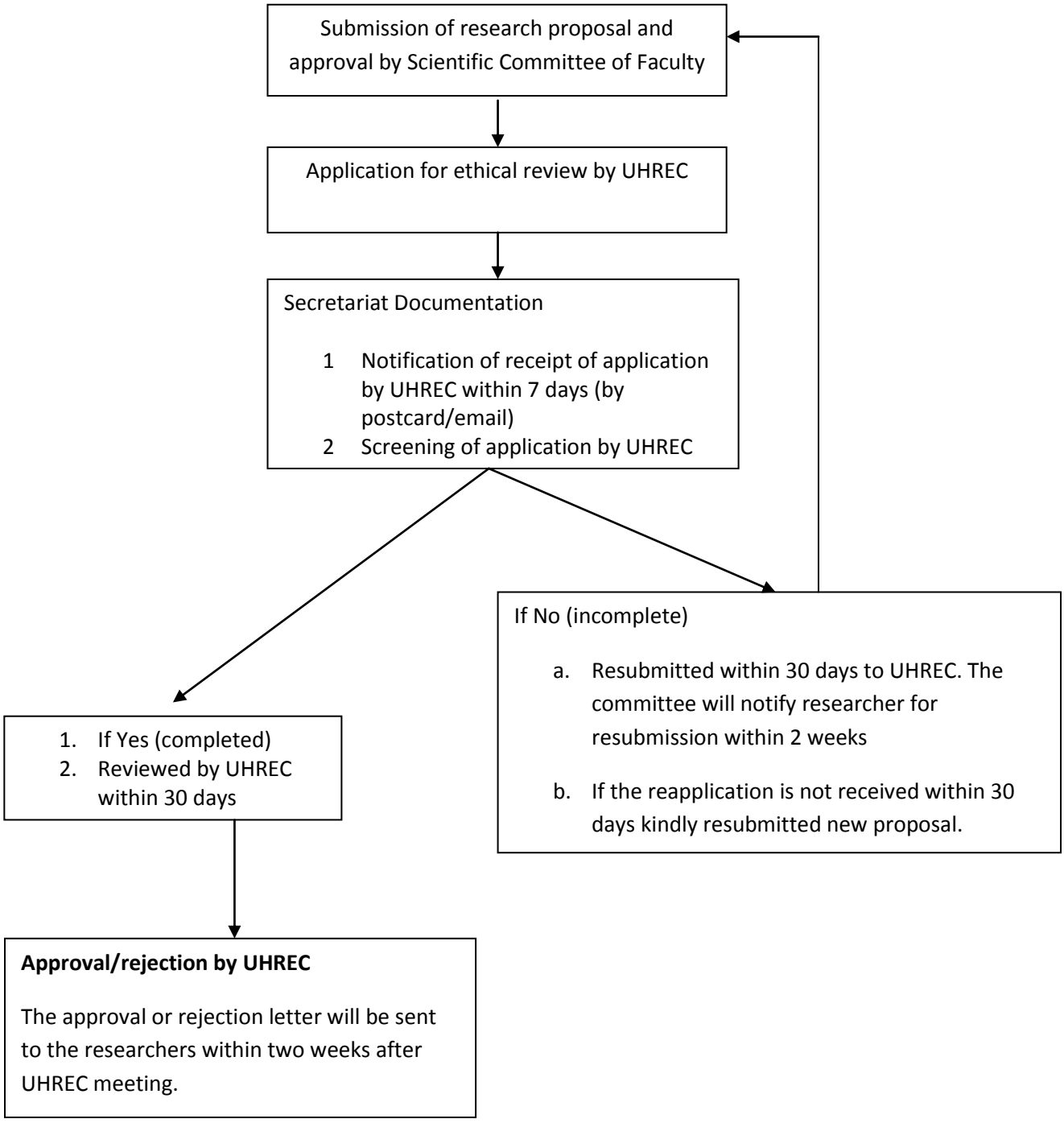
Appendix A

ORGANIZATIONAL CHART OF UHREC



Appendix B

STANDARD OPERATING PROCEDURE (SOP) OF UHREC



Appendix C

APPLICATION FOR ETHICAL REVIEW

For official use	
Application No	: UniSZA.N/UHREC/2012/
Date Received	:
Reviewed By Scientific Committee of Faculty	:
Meeting Date	:
Decision Date Informed	:

1. TITLE OF PROJECT

2. INVESTIGATORS

a. *Please attach the Curriculum vitae*

Title: Mr/Ms/Dr/Assoc. Prof/Prof/Dato`:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact no:
Email address:
Principal Investigator/Co-investigator/Supervisor:
Signature:

Title: Mr/Ms/Dr/Assoc. Prof/Prof/Dato`:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact no:
Email address:
Principal Investigator/ Co-investigator/ Supervisor:
Signature:

Title: Mr/Ms/Dr/Assoc. Prof/Prof/Dato`:
Name:
Qualifications:
Designation:
Place of Work:
Address:
Contact no:
Email address:
Principal Investigator/ Co-investigator/ Supervisor:
Signature:

Applications from investigators based in overseas will only be considered if the project is conducted in collaboration with investigators based in Universiti Sultan Zainal Abidin who should take equal responsibility for the conduct of the study.

3. PROJECT PROTOCOL (*see attachment of Research Grant Application Forms)*

a. Background

A brief explanation of the project and literature review. Please append if more space is required.

b. Objectives

c. Expected Benefits

d. Duration

e. Location

f. Methodology

i. Experimental design and methodology
ii. Sample size and selection criteria
iii. Division of test and control groups, cohort properties or samples, and type of control
iv. Data handling

4. RESEARCH GRANT *[Please Tick (√) where applicable]*

☐ Funding obtained ☐ Funding in progress

a. If funding has been secured, please state the source:

b. Total allocation

c. Duration of study grant

5. DOCUMENTS FOR CONDUCT OF RESEARCH STUDY AND FOR ETHICAL APPROVAL *[Please Tick (√) where applicable]*

☐ Clinical Study Protocol

☐ Respondent Information Sheet

☐ Consent Form

☐ Investigator`s Brochure

☐ Letter of Indemnity

☐ Payment Method

☐ Method of Advertisement

☐ List of Drug

☐ Case Report Form

6. REVIEW REQUESTED

☐ Ethical approval

7. Comment by UHREC Chairman

☐ **APPROVED**

_____
Prof. Dato' Dr. Ahmad Zubaidi A. Latif
Chairman

☐ **APPROVED AFTER REVISION**

☐ **REJECTED, REASONS: _____**

Resubmission should be made within 30 days. Resubmission after 30 days is null and void

STUDY PROTOCOL OF A RESEARCH PROJECT

An example is research brochure study information sheet and or reciprocal information for researchers and participants.

Title of a Project

Pharmacokinetics interactions between propranolol and durian

Purpose of study

To compare the bioavailability of propranolol taken with durian.

Subjects

Eighteen healthy human volunteers, aged between 18 and 45 years of normal weight for height will be included in the study. Each subject will undergo a medical examination including haematology, blood chemistry and urinalysis.

Subject Exclusions

Individuals with a history of known hypersensitivity to propranolol, hyperkalaemia, cardiovascular, liver, kidney, respiratory diseases or other major medical illnesses will be excluded from the study. Subjects predisposed to diabetes mellitus will also be excluded. Also any subject with laboratory results more than two standard deviations from the mean normal value for the laboratory running the tests should be excluded. Alcoholics, heavy smokers (more than 6 cigarettes or equivalent per day), drug addicts, obese individuals, pregnant women or lactating mothers will also be excluded.

Subject Considerations

The purpose of the study will be fully explained to each subject by the study co-coordinator. The study co-coordinator will explain to each subject the risk involved in participating in the study including the effects of the drug and blood sample collection. The study co-coordinator will offer to answer any questions a subject may have concerning the study. Each subject will be paid RM100 per study phase to compensate them for their time and inconveniences. It is felt that this amount is not excessive as to cause unusual inducement to enter the study. Each subject will be told that their participation may be terminated by themselves without prejudice or by the medical supervisor or study co-coordinator. Each subject will be asked to sign a form of consent indicating their willingness to participate in the study.

Adverse Reactions of Propranolol

Propranolol is usually well tolerated. The most frequent type of adverse reaction occurring with propranolol is gastrointestinal complaints include nausea and vomiting, diarrhoea and other gastrointestinal disturbances: weakness, dry mouth and rash may also occur. Others include sleep disturbances, sedation, asthma and cardiac disturbances. Elevation of triglycerides and diminished high-density lipoprotein levels may also occur.

Study Design

It is a randomized control double dummy cross over study of propranolol and propranolol with durian. The study will be in 2 stages:

First: The subjects will take either 2 x 40 mg tablets of propranolol

Second: 2 x 40 mg tablets of propranolol will be administered at the same time with durians x 200g

Randomization of 18 subjects	First Dosing Day		Second Dosing Day
For 9 subjects selected randomly	Control Tablet Propranolol	2 weeks washout period	**Test** Tablet Propranolol + durian
For 9 subjects selected randomly	**Test** Tablet Propranolol + durian		Control Tablet Propranolol

Ten millilitre of blood will be collected from an indwelling venous cannula or by repeated venipuncture, at predose (0 min) and at 30 minutes, 1, 1.5, 2, 3, 4, 6 and 8 after drug administration. Each blood sample will be centrifuged and plasma separated and kept frozen until analysis. Each plasma sample will be analysed by ultra-performance liquid chromatography. The plasma concentration–time data will be statistically analysed to compare bioavailability of propranolol ingested with durian.

Academic Supervisor

Prof Dr Zabidah Ismail

Medical Supervisor/Clinical Supervisors

a. Assoc. Prof. Dr Shahruddin Abdullah
b. Dr. Mohd Izham Ishak (IC 810526-02-5777)
c. Dr Mohamad Che' Man
d. Dr Norazlina Juhari
e. Assoc. Prof. Dr. Tarik Ibrahem Ali
f. Assoc. Prof. Dr. Ahmed Ghazi Faisal

Appendix E

SAMPLE CONSENT FORM

UNIVERSITI SULTAN ZAINAL ABIDIN
FACULTY / DEPARTMENT OF .....

Consent form for persons participating in research projects

PROJECT TITLE:.....

Name of participant/IC Number:
Name of investigator(s)/IC Number:

1. I consent to participate in the project named above, the particulars of which – including details of.....*(include terms relevant to the methodology of the research. e.g., "test or procedures", "interviews and questionnaires")* – have been explained to me. A written copy of the study protocol has been given to me to keep. (*see appendix B*)

2. I authorize the researchers or collaborators to use the findings for publications/patency/product development and improvement

3. I acknowledge that:

a) The possible effects of the research study have been explained to me to my satisfaction.

b) I have been informed that I am free to withdraw from the project at any time without any explanation or prejudice to me and the researchers and collaborators withdraw all data pertaining to me

c) All necessary precaution has been taken to reduce or prevent potential hazards or side effects. In unfortunate circumstances I will be treated by the doctors in charge.

d) I have been informed that the confidentiality of the information I provide will be safeguarded subject to any legal requirements.

e) The researchers can keep freeze, used or dispose research products with condition that my name remains private and confidential

f) Pseudo name will be used in publication or presentations arising from the research.

g) My participation will not influence my credential (grades, assessment and employment).

h) I have read and understood the description of the above-named project. On this basis I agree to participate as a subject in the project, and I consented to any publication of the results of the project with the understanding that anonymity will be preserved.

i) The researchers and collaborators are not responsible for any unfortunate circumstances and not liable for litigation

Name :

(Participant)

Signature:

Date :

Name :

(Researcher/Collaborator)

Signature:

Date :

Name :

(Parent/Guardian/Caretaker)

Signature:

Date :

Where participants are less than 18 years of age, space needs to be provided for the parent/guardian to sign the consent form. For some research it may be more appropriate to develop separate consent forms for the child and the parent/guardian.

Appendix F

Meeting Schedule of UHREC 2012

Meeting No.	**Meeting Date (2012)**	**Meeting Time (am)**	**Deadline of Submission of Application**
1/2012	28 June 2012	11:00	28 May 2012
2/2012	26 July 2012	11:00	26 Jun 2012
3/2012	30 August 2012	11:00	30 July 2012
4/2012	27 September 2012	11:00	27 August 2012
5/2012	25 October 2012	11:00	25 September 2012
6/2012	29 November 2012	11:00	29 October 2012
7/2012	27 December 2012	11:00	27 November

UHREC will meet once a month as the date stated.

Appendix G

RESEARCH SCREENING FORM
UniSZA HUMAN RESEARCH ETHICS COMMITTEE (UHREC)

Principal Investigator : _____

Project Title : _____

Department : _____

*** Please Tick [√] if YES, [X] if NO, and [O] if NOT APPLICABLE**

No	Items	Applicant	Internal Assessor	Comments	UHREC Member	Comments
1.	The title is appropriate					
2.	Has a similar study been done before? If YES, a) The novel elements in the present study have been stated b) Findings from previous studies have been stated If NOT, a) There is sufficient justification					
3.	Standard therapy is stated					
4.	a) Main objectives is clear					
	b) Specific objective are clear					
5.	The hypothesis (ses) is/are clear					
6.	The study population is clearly stated					
7.	The sample size calculation is shown & appropriate					
8.	The study design is clearly described					
9.	The study sites is/are clear stated					

10.	The names of the co-investigators are clearly stated & appropriate					
11.	The inclusion and exclusion criteria are stated & appropriate					
12.	Drug Control Authority (DCA) approval is required and has been obtained					
13.	A flow chart of the study methodology is enclosed					
14.	The are no major ethical issues in the study					
15.	Approval from at her relevant authorities, eg institution of co-investigators, ministries, etc has been obtained					
16.	The study budget is appropriate					
17.	The subject information sheet is easy to understand and follow the MRIS format					
18.	The consent form is clear and follow the MRIS format					
19.	The questionare(s) have(have) been validated (for all versions used)					
20.	Intellectual Property Rights (IPR) agreement needed and enclosed					

Decision :

Internal Assessor
Approve [ ]
Revise & Resubmit [ ]
Revise & Present [ ]

Signature :
Name :
Date :

UHREC Member
Approve [ ]
Revise & Resubmit [ ]
Revise & Present [ ]

Signature :
Name :
Date :

BORANG MAKLUMBALAS

KELULUSAN ETIKA PENYELIDIKAN MANUSIA UNIVERSITI SULTAN ZAINAL ABIDIN (UHREC) – MELALUI EDARAN

MESYUARAT ETIKA PENYELIDIKAN MANUSIA UNISVERSITI SULTAN ZAINAL ABIDIN (UHREC) BIL. 6/2012

		Setuju	Tidak Setuju
a.	Preliminary Study on Polymorphisms of Peroxisome Proliferator Activated Receptor Alpha (PPARα) Gene in Fasting.	☐	☐
b.	Study 'Pharmakokinetics Interaction of Propranolol and Durians'	☐	☐
c.	Nutritional Status of Pulmonary Tuberculosis Patients in Kuala Terengganu	☐	☐
d.	Energy Cost of a Predetermined Physical Activity in Subjects of Three Nutritional Status	☐	☐
e.	Nutritional Assessment Among Universiti Sultan Zainal Abidin (UniSZA) Staff	☐	☐
f.	Nutritional status, body composition, physical activity level and nutritional knowledge, attitude, practice (KAP) among undergraduate health science female students at Universiti Sultan Zainal Abidin	☐	☐
g.	Glycemic Index of Selected Breakfast Meals and Local Kuih Commercially Available in Kuala Terengganu	☐	☐
h.	Nutritional Status and Metabolic Adaptation During Ramadan Among Higher Institution Learning Centre (UniSZA) Staffs with Different Weight Status	☐	☐

**sila tandakan (/) pada yang berkenaan*

NAMA : _____

JAWATAN : _____

TARIKH : _____

TANDATANGAN :