

#### **Al Nasser University** FACULTY OF MEDICINE

#### Medical ethics committee Al Naser University faculty of Medicine

## MEDICAL ETHICS COMMITTEE AL NASER UNIVERSITY FACULTY OF

	(Application to Conduct Research Project)
(Project title):	
2.Principal investigator):	:
2.1 Nama (Name):	
<ul><li>2.2 Designation:</li><li>2.3 Department): Department of Pharmacy, Faculty of Medicine</li></ul>	
Please attach your brief	CV
Other investigators:	
Nama (Name)	(Designation & Department)

New continuation

If it is a continuation project, please give details as follows:

- (Initial project title [if applicable])
- Date of commencement)
- (Date of completion
- Previous sponsorship
- Amount of sponsorship)

#### Please state whether this project is for fulfilment of basic/postgraduate degree)

State name of degree, e.g Bachelor, Master or PhD)

No



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#### Research funding (State source of funding)

- No funding needed
- To apply later
- Trial sponsor
- State name of sponsor
- Research fund
- Name of fund



#### **Project information:**

Background, literature reference and rationale for this project)

- Background
- literature reference
- rationale for this project)

(Objectives of the Project)

(Expected outcome, if any)

Significance and/or further practical applications, if any

Time frame for project, including duration, phases, start date and end date estimates)

#### **ACTIVITIES**

TIME LINE

- Literature review
- Writing protocol
- Applying for ethical approval
- study
- Submitting a review paper for publication
- Refining protocol
- Patient recruitment and data collection
- analysis
- Tool development
- Tool evaluation
- Journal article write up and submission
- Thesis write up
- Thesis submission



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#### **Proposed methodology**

Study design (Please submit explanatory notes/appendices if necessary) (Please give details concerning population or materials to be studied, procedures, and data processing methods etc)

- Study design
- Setting and outcomes
- Population to be studied
- Material to be studied
- Procedure
- Statistical analysis
- Data collection technique involved:
  - a. Prospective
  - b. Retrospective
  - c. Other technique (Please specify):

#### Are human subjects involved?

- yes
  - ✓ please select:
  - ✓ patients
  - ✓ state number of patient
  - **✓** Volunteers or Normal controls
  - **✓** Survey of target groups (Please attach questionnaire)
- No

#### Are new therapeutic procedures/drugs being tested?

- Yes
- No

#### Are invasive procedure applied

- Yes, state the procedure
- No



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#### Will resources/ equipment in FOM or UMMC be utilized? If yes, please state

Yes

Library database, PCR optimized amplification refractory mutation system, Data Base of Medical records

• No

#### **Ethical Issues**

Does this project conform to the Declaration of Helsinki/Malaysian Good Clinical Practice (GCP) Guidelines?

What are the risks to the research subjects of this study?

(How is coverage for Serious Adverse Events (SAEs) (eg: insurance, payment, etc) provided for?)

What are the benefits to research subjects of this study?)

Will beneficial treatment still be provided for research subjects after completion of the study? If no, please state why)

- Yes
- No

#### Will information to the patient and informed consent be provided?

- Yes
   (please fill in Patient Information Sheet and Consent Form provided)
- NO

(Other information)



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(Are expenses borne by the research subjects? If yes, please state the expenses
incurred. If no, how are expenses provided for?)

- Yes
- No

	(Will any form of payment be offered to research subjects? If yes, what is the
١,	amount?)

- Cor
- YesNo
- Signature of Applicant

(Date) (Signature)
(Name in Full)

• (Comments of Head of Department)

(Support/Not supported)



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(Date)	(Signature & Stamp of Head of Department)
	(8-8