Al-Nahrain University
College of Medicine

Institutional Review Board (I.R.B.)

1 Project's full title:

2 Type of the project:

If 'Others', what?

3 Has this study been done elsewhere?

Yes No

If 'Yes', please list titles of the most similar researches and date of publication:

4 Time schedule:

Proposed starting date of the study: 01/09/2015

Proposed completion date of the study: 31/12/2016

5 Location(s) where the research is to be conducted?

6 Goals of the research:

a) What are the objectives of the study?

b) What is the research justification for the country?

7 This project will involve the following subject types:

Normal Volunteers In-patients Out-patients Patient Controls
Students Cognitively Disabled Pregnant Women Prisoners or Institutionalized Individuals
Fetuses Infants (0–3 y) Children (3–18 y) Geriatrics>70 y

8 How will you deal with human subjects?

Not applicable
Gathering Information
Taking Sample
Intervention (drug, device, etc...)
Others
How?

9 Subjects:

a) Research population and sample size calculation

b) Study design
Correlational Cross-sectional Case-control Prospective Cohort
Retrospective Cohort Randomized Clinical Trial
Qualitative Social Study Others

c) How will study subjects be selected in the study?
Randomized Selection Non-randomized Selection

10 Health hazards

Are there any predictable risks to the subjects of physical or psychological pain or discomfort, or risk of injury of any kind? Yes No Cannot predict
If 'Yes' or 'Cannot predict', describe the possible areas of risk. Outline briefly any steps taken to minimize the possibility of pain, discomfort or injury and procedures for determining levels of discomfort at which you will terminate the participation by the subject in the research:

11 This project involves the use of:

Not applicable
(check mark all that apply to the study)

a) An Investigational New Drug (IND) or an approved drug for an unapproved indication . Please mention the drug name and company:

b) An Investigational Medical Device or an Approved Medical Device for an unapproved use . Please mention the device name and manufacturer:

c) Radiation or Radioisotopes

d) Blood/Body Fluid: Total Amount of Blood/Fluid
Frequency of taking:

e) Recombinant or Bio-hazardous Materials

f) Human Tissue or Cell Lines

12 In case a drug (pharmaceutical or herbal) or a device will be used in the study:

Not applicable

a) Is the drug or the device approved (registered) by Ministry of Health (MOH)?
Yes No
If 'No', is the drug or the device approved by any major International Organizations, e.g. FDA, EMEA?
Yes No

b) Provide details of any known side effects, which may result from the investigational drug or device:

c) If it is a drug, what phase of research the drug has reached to date?
Phase 1 Phase 2 Phase 3

13 Is this a double-blind study?

Yes No If 'Yes',

a) Is the code for unblinding in case of emergency available at both the investigator and supervisor?
Inestigator Supervisor Both

b) In which format are code breaks for clinical trials supplied?
Sealed Envelopes Scratch Cards Tear-off label on the drug container which will be removed when dispensing the trial drug and place on the drug accountability form

14 Please specify any incentives, compensation or treatment the participants will receive through participation in this study:

Not applicable

15 Please specify any conflict of interest, conflict with religion, or conflict with low or social obligations:

16 Does the project require any examination or use of patients medical records?

Yes No

a) If 'Yes', please tick the required data element(s):
Entire Medical Record Pathology Report Operative Reports
Laboratory Reports Length of Stay Consultations
Outpatient Clinic Records Discharge Summary Dental Record
Emergency Dept. Report History & Physical Examination
Progress Notes Diagnostic Imaging Reports Principal Diagnosis

Secondary Diagnosis Principal Procedure(s) Secondary Procedure(s)
Police Reports Post-mortem Reports
Others

b) Does the data relate to any sensitive issues (Such as HIV/AIDS, STD, sexual assault or child abuse)? Yes No

c) Will the information be recorded in such a manner that subjects can be identified? Yes No

17 Informed consent:

a) When will informed consent be obtained from the subjects?
(Please specify the time)

b) For medical records; have you signed a Statement of Confidentiality? (Statement of Confidentiality should be signed by all individuals who will have access to the medical records)
Yes No

18 Protocol

18.1 Background

18.2 Aim of the Study

18.3 Methodology

18.4 References

19 Principal investigator

Name:

Department: Institution:

Contact Mobile No.: E-Mail:

Your signature indicates that you agree to abide by all policies, procedures, regulations and laws governing the ethical conduct of research involving human.

Signature Date

20 First supervisor

Not applicable

Name: Title:

Department: Institution:

Contact Mobile No.: Office:

E-Mail:

Your signature indicates that you have reviewed and approved the proposal, assisted the student in the preparation of this application and agree to be responsible for the ethical aspects of the project.

Signature Date

21 Second supervisor

Not applicable

Name: Title:

Department: Institution:

Contact Mobile No.: Office:

E-Mail:

Your signature indicates that you have reviewed and approved the proposal, assisted the student in the preparation of this application and agree to be responsible for the ethical aspects of the project.

Signature Date

22 Consultant

Not applicable

Name: Title:

Department: Institution:

Contact Mobile No.: Office:

E-Mail:

Your signature indicates that you have reviewed and approved the proposal, assisted the student in the preparation of this application and agree to be responsible for the ethical aspects of the project.

Signature Date

23 IRB decision:

Accepted Rejected

IRB Seal Date IRB Head Name

24 IRB approval

IRB Member Name	IRB Member Name	IRB Member Name	IRB Member Name
Date	Date	Date	Date
Signature	Signature	Signature	Signature

Reset Print

IRB e-mail address: irb@colmed-alnahrain.edu.iq