IRAQI BOARD OF MEDICAL SPECIALIZATIONS

Chairman Deputy for Scientific Affairs Office

INSTITUTIONAL REVIEW COMMITTEE OF RESEARCH PROJECTS (I.R.C.R.P)

1 Project's full title:

2 Type of the project:

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:

Proposed completion date of the study:

5 Centre(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) Study design

Correlational Cross-sectional Case-control Prospective Cohort

Retrospective Cohort Randomized,Clinical.Trial

Qualitative Social Study Others

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

Not applicable

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

15 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

16 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

17 Protocol

17.1 Background

17.2 Aim of the Study

17.3 Methodology

17.4 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 IRC decision:

Accepted Rejected

IRC Seal Date IRC Head Name

24 IRC approval

IRC Member Name	IRC Member Name	IRC Member Name	IRC Member Name
Date	Date	Date	Date
Signature	Signature	Signature	Signature

Reset Print