King Saud University

College of Medicine

Course CMED 305

COURSE MANUAL

1438-39 (2017-2018)

Contents

Coordinators' message

Dear Colleagues / 3rd Year Students

Assalamoalaikum wa rehmatullah

Welcome to CMED 305 course.

It is a pleasure to work with 3rd year undergraduate students and esteemed faculty members of College of Medicine at King Saud University as instructors for course and supervisors for research work.

The attached document is a complete course outline along with certain guidelines that are meant to be used by students, instructors and research supervisors. This document is a useful reference as the course work is constructed linking the concepts in research methods, skill learning, and stage of research work. The construction of course this year is based largely on feedback from students, and faculty members based on last year's experience.

We are sure that this year also you will enjoy conducting a relevant research work that is beneficial to patients, population, institution, and region. Your hard work will be cherished as a useful outcome extending knowledge and enhancing skills in students at College of Medicine. This document contains the list of titles of last 4 years research projects done by students, for your easy reference.

We are thankful to Dr Ali Al-Hazmi and Dr. Nourah for their advice in academic content and organization of this course. The course content and all documents were approved by Community Medicine Unit, KSU Department of Family & Community Medicine. We highly acknowledge the support from Dr.Mona, Head, KSU Department of Medical Education, in facilitating the course schedule and logistics.

Wish you a very productive academic year

Dr Shaffi Ahmed, Course Co-ordinator
Dr.Shatha Ahmed Alduraywish, Co-coordinator
Department of Family & Community Medicine

September 17, 2017

Course Objectives

The overall objectives of this course are to enable students understand basic elements of research, design and conduct an **epidemiological study** to answer a specific research question.

Learning Methods

Learning methods include lectures (31 hours), tutorials (33 hours), and research group meetings (30 contact hours). Course is equivalent to six academic credits. Self-initiatives and learning is important.

The course consists of following concepts that will be taught is lectures and tutorials;

- How to formulate a research question and development of a study protocol
- Epidemiological study design methods and assessment of risks in comparison to no risk
- Ethics and plagiarism
- Biostatistics concepts and skills in data management & analysis
- Data interpretation, discussion, & presentation of study findings and conclusion

The Research Group Meetings with the research supervisor will focus on the entire process of above mentioned concepts to be linked with a specific topic. **The Research Supervisor, who is a faculty or expert in the specific topic of interest, will help you to learn subject concepts as well as formulate the research question, and supervise the development of protocol, monitor the conduct the study, using appropriate epidemiological and ethical methods.**

Assessment Methods

Marks Distribution *:

I. Examinations (40%)
   Midterm: 15%
   Final exam: 25%

II. Continuous Assessment (60%)
   Research Project (40%):
      Research protocol: 10%; (by Research supervisor)
      Ethical Review Clearance: 5% (by Review committee)
      Final report: 20% (10% by Research supervisor & 10% by Community Medicine Unit Review committee)
      Presentation: 5% (by independent evaluators)
   Other assignments / quizzes (20%):
      Assignments (10%); Quizzes (10%)

CMED 305 Course Schedule (2017-2018)

	Schedule for Course CMED 305 / 1438 - 1439 (2017-2018)					
	Males A Date/Time	**Males B Date/Time**	**Females Date/Time**	**Lectures/Tutorials Part I**	**Instructors-Males**	**Instructors-Females**
Week 1	**19/09/2017**	**19/09/2017**	**20/09/2017**	Introduction to Research methods: Why do we need research?	Dr Shaffi Ahamed	Dr.Nourah
	2:00 – 3:00	8:00 – 9:00	2:00 – 3:00			
	Formulation of research groups by students & selection of supervisors					
	20/09/2017	**20/09/2017**	**21/09/2017**	How to develop a research protocol?	Dr Shaffi Ahamed	Dr.Shaffi Ahamed
	9:00 –10:00	11:00-12:00	8:00 – 9:00			
Week 2	**26/09/2017**	**25/09/2017**	**25/09/2017**	Research questions, objectives and hypotheses	Dr Shaffi Ahamed	Dr.Shatha
	8:00 – 9:00	8:00 – 9:00	9:00 –10:00			
	26/09/2017	**25/09/2017**	**26/09/2017**	**Practical Session: Research questions, objectives and hypotheses**	**Dr.Hani**	**Dr Haifa Wahab/Dr.Shatha**
	1:00 – 2:00	2:00 – 3:00	8:00 – 9:00			
	26/09/2017	**26/09/2017**	**27/09/2017**	**Research Groups meet with potential supervisors and confirm**	**Research Supervisor**	
	2:00 – 3:00	3:00 – 4:00	8:00 – 9:00			
	27/09/2017	**28/09/2017**	**28/09/2017**	Ethics in health research	Prof.Jamal Jarallaha	Prof.Randa Yousef
	11:00-12:00	8:00 – 9:00	9:00 – 10:00			
	27/09/2017	**27/09/2017**	**28/09/2017**	**Practical Session: How to do Literature Search?**	**Dr.Hani**	**Dr Haifa Wahabi/ Dr Rufaidah**
	1:00 – 3:00	10:00-12:00	10:00-12:00			
Week 3	**03/10/2017**	**01/10/2017**	**05/10/2017**	**Research Group meets with supervisor**	**Research Supervisor**	
	2:00 – 3:00	1:00 – 2:00	9:00 – 10:00			
	04/10/2017	**02/10/2017**	**05/10/2017**	Introduction to Study Designs	Dr. Ibrahim Gosadi	Dr.Randa Yousef
	8:00 – 9:00	1:00 – 2:00	10:00-11:00			
	04/10/2017	**02/10/2017**	**04/10/2017**	Measures of Disease Frequency, Effect & Impact	Dr. Ibrahim Gosadi	Dr.Salwa Tayel
	9:00 –10:00	2:00 – 3:00	1:00 – 2:00			
	04/10/2017	**03/10/2017**	**04/10/2017**	**Practical Session: Measuring Risk, Incidence & Prevalence**	**DrAlMouzam**	**Dr.Rufaidah**
	10:00-11:00	3:00 – 4:00	2:00 – 3:00			
	05/10/2017	**04/10/2017**	**04/10/2017**	Cross Sectional Study Design	Dr. Ibrahim Gosadi	Dr Salwa Tayel
	3:00 – 4:00	10:00-11:00	3:00 – 4:00			
	Submission of Supervisor Agreement Form ()					
Week 4	**09/10/2017**	**09/10/2017**	**11/10/2017**	Case Control study Design	Dr. Ibrahim Gosadi	Dr Randa Yousef
	9:00 –10:00	1:00 – 2:00	1:00 – 2:00			
	11/10/2017	**11/10/2017**	**12/10/2017**	**Practical Session: Odds Ratio & Minimizing Bias**	**Dr AlMouzam**	**Dr Salwa Tayel**
	9:00 –10:00	1:00 – 2:00	10:00-11:00			
	11/10/2017	**11/10/2017**	**12/10/2017**	**Research Question, Objectives,& Hypothesis, &**	**Research Supervisor**	

	10:00-11:00	11:00-12:00	11:00-12:00	**potential design**		
	Submission of Study Title, Research Question, Objectives, Hypothesis & Potential Design					
Week 5	**16/10/2017**	**15/10/2017**	**18/10/2017**	Cohort Study Design	Dr.Ali Hazmi	Dr Rufaidah
	8:00 – 9:00	1:00 – 2:00	1:00 – 2:00			
	17/10/2017	**15/10/2017**	**18/10/2017**	Experimental Study Design	Dr.Ali Hazmi	Dr Haifa Wahabi
	8:00 – 9:00	2:00 – 3:00	2:00 – 3:00			
	17/10/2017	**16/10/2017**	**19/10/2017**	**Practical Session: Relative Risk, Confounding**	**Dr AlMouzam**	**Dr.Shatha/Dr.Afnan**
	2:00 – 4:00	2:00 – 4:00	8:00 – 10:00			
	18/10/2017	**17/10/2017**	**18/10/2017**	**Research group works on organizing lit search- Introducing the topic**	**Research Supervisor**	
	9:00 –10:00	8:00 – 9:00	3:00 –4:00			
	18/10/2017	**18/10/2017**	**19/10/2017**	What is Plagiarism? How to avoid it?	Prof.Sultan Meo	Dr Randa Yousef
	10:00-11:00	8:00 – 9:00	10:00-11:00			
	19/10/2017	**19/10/2017**	**19/10/2017**	Writing an Introduction of a research protocol	Prof Hamza AbdulGhani	Dr.Hafsa
	11:00-12:00	9:00 –10:00	11:00-12:00			
	Research Groups get the feedback on research question/objectives/hypothesis by the Core group of faculty members					
Week 6	**23/10/2017**	**22/10/2017**	**19/10/2017**	**Practical Session: How to write an introduction for research study?**	**Dr. AlMouzam**	**Dr Hafsa Raheel/Dr.Afnan**
	8:00 – 9:00	9:00 –10:00	3:00-4:00			
	22/10/2017			**MIDTERM EXAMINATION**		
	1:00 – 3:00					
	25/10/2017	**23/10/2017**	**22/10/2017**	**Research Groups review the feedback**	**Research Supervisor**	
	9:00 –11:00	2:00 –4:00	10:00-12:00			
	25/10/2017	**23/10/2017**	**24/10/2017**	Qualitative Study Designs	Dr.Ibrahim Gosadi	Dr.Noora
	11:00-12:00	1:00 – 2:00	1:00 – 2:00			
	26/10/2017	**24/10/2017**	**25/10/2017**	Tools for data collection: Using Questionnaire & other tools	Dr.Ibrahim Gosadi	Dr Randa Yousef
	3:00 – 4:00	8:00 – 9:00	1:00 – 2:00			
	26/10/2017	**25/10/2017**	**26/10/2017**	**Research Group works on study design & finalizing study objectives**	**Research Supervisor**	
	1:00 – 3:00	1:00 – 3:00	10:00-11:00			
Week 7	**29/10/2017**	**31/10/2017**	**30/10/2017**	Sampling Techniques	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	9:00 –10:00	8:00 – 9:00	8:00 – 9:00			
	30/10/2017	**31/10/2017**	**30/10/2017**	**Practical Session: Designing questionnaire & Study Tools**	**Dr AlMouzam**	**Dr. Hafsa Raheel/Dr.Rufaidah**
	10:00-12:00	9:00 –11:00	9:00 –11:00			
	31/10/2017	**01/11/2017**	**01/11/2017**	**Practical Session: How to apply Sampling Techniques?**	**Dr AlMouzam**	**Dr.Rufaidah**
	1:00 – 3:00	8:00 – 10:00	1:00 – 3:00			
	01/11/2017	**02/11/2017**	**02/11/2017**	**Practical Session: Selection of Study Design**	**Dr.Hani**	**Dr.Afnan**
	8:00 – 9:00	8:00 – 9:00	8:00 – 9:00			
	01/11/2017	**02/11/2017**	**14/11/2017**	**Research Group finalizes study design & develop study questionnaire/ tools**	**Research Supervisor**	
	10:00-11:00	9:00 –10:00	10:00-12:00			
	01/11/2017	**30/10/2017**	**02/11/2017**	Sample Size Estimation	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	11:00-12:00	1:00 – 2:00	9:00 – 10:00			

	01/11/2017	**30/10/2017**	**02/11/2017**	How to write Materials & Methods Section of a Research Protocol	Prof Hamza AbdulGhani	Dr Randa Yousef
	1:00 – 2:00	2:00 –3:00	10:00-11:00			
	02/11/2017	**13/11/2017**	**13/11/2017**	**Practical Session: How to calculate Sample Size?**	**Dr.Shaffi**	**Dr.Raufaidah**
	8:00 –10:00	1:00 – 3:00	1:00 – 3:00			
	12/11/2017	**15/11/2017**	**15/11/2017**	**Research Group works on writing methods & finalizes questionnaire/tools**	**Research Supervisor**	
	10:00-12:00	8:00 – 10:00	1:00 – 2:00			
	13/11/2017	**14/11/2017**	**15/11/2017**	Institutional Review Board (IRB) application for Ethical Approval	Prof Sulaiman	Dr Salwa Tayel
	8:00 – 9:00	8:00 – 9:00	8:00 – 9:00			
Week 9	**14/11/2017**	**15/11/2017**	**15/11/2017**	**Practical Session: How to Write Study Methods?**	**Dr.Hani**	**Dr. Haifa Wahabi**
	10:00-11:00	1:00 – 2:00	9:00 – 10:00			
	15/11/2017	**16/11/2017**	**15/11/2017**	**Practical Session: How to apply to IRB for Ethical Approval?**	**Dr AlMouzam**	**Dr Salwa Tayel**
	8:00 – 9:00	8:00 – 9:00	11:00-12:00			
	15/11/2017	**19/11/2017**	**27/11/2017**	**Research group works with research supervisor finalizing IRB application**	**Research Supervisor**	
	10:00-12:00	1:00 – 3:00	1:00 – 3:00			
	16/11/2017	**20/11/2017**	**16/11/2017**	Basic concepts and terminology in biostatistics	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	8:00 – 9:00	1:00 – 2:00	9:00 – 10:00			
Week 10	**20/11/2017**	**20/11/2017**	**29/11/2017**	**Working with Research Supervisor**	**Research Supervisor**	
	8:00 – 9:00	2:00 – 3:00	1:00 – 3:00			
	Research Groups Submit Research Proposal for Fast Track ERC (Data Collection initiated after ERC approval) Evaluation by Supervisor (Form A)					
	21/11/2017	**22/11/2017**	**19/11/2017**	Description of Data: I (Summary measures / central tendency)	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	8:00 – 9:00	1:00 – 2:00	10:00-11:00			
	22/11/2017	**22/11/2017**	**19/11/2017**	Description of Data II: (Measures of Variability / Normal distribution)	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	9:00 –10:00	2:00 – 3:00	11:00-12:00			
	22/11/2017	**23/11/2017**	**22/11/2017**	**Practical Session: How to describe your data?**	**Dr.Shaffi**	**Dr.Raufaidah**
	10:00-12:00	1:00 – 3:00	1:00 – 3:00			
Week 11	**Research Groups Receive Feedback from Fast Track ERC (Data Collection initiated after ERC approval)**					
	28/11/2017	**26/11/2017**	**27/11/2017**	**Discussion with supervisor on ERC submissions/resubmissions if any**	**Research Supervisor**	
	2:00 – 3:00	1:00 – 2:00	1:00 – 3:00			
	29/11/2017	**27/11/2017**	**04/12/2017**	**Discussion with supervisor on ERC feedback/ initiate data collection / resubmissions if any**	**Research Supervisor**	
	9:00 –11:00	2:00 – 4:00	1:00 – 3:00			
	29/11/2017	**29/11/2017**	**28/11/2017**	Statistical Significance of Data I (P value)	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	1:00 – 2:00	11:00-12:00	8:00 – 9:00			
Week 12	**07/12/2017**	**04/12/2017**	**29/11/2017**	Statistical Significance of Data II (95% CI)	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	11:00-12:00	1:00 – 2:00	8:00 – 9:00			
	07/12/2017	**07/12/2017**	**07/12/2017**	**Practical Session: Statistical Significance**	**Dr .Shaffi**	**Dr.Afnan**
	1:00 – 3:00	8:00 – 10:00	10:00-12:00			
Week 13	**12/12/2017**	**10/12/2017**	**14/12/2017**	**Data Collection Continues - Monitoring by Research Supervisor**	**Research Supervisor**	
	2:00 – 3:00	1:00 – 2:00	10:00-11:00			

	13/12/2017	**11/12/2017**	**13/12/2017**	Statistical Tests for quantitative variables	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	8:00 – 9:00	2:00 – 3:00	1:00 – 2:00			
	13/12/2017	**11/12/2017**	**14/12/2017**	Statistical Tests for qualitative variables	Dr Shaffi Ahmed	Dr Shaffi Ahmed
	9:00 –10:00	3:00 – 4:00	9:00 –10:00			
	13/12/2017	**13/12/2017**	**28/12/2017**	**Data collection/management**	**Research Supervisor**	
	11:00-12:00	9:00 –10:00	10:00-12:00			
Week 14	19/12/2017	28/12/2017	10/12/2017	**Data collection Management**	**Research Supervisor**	
	8:00-9:00	8:00-9:00	2:00-3:00			
	21/12/2017	**17/12/2017**	**20/12/2017**	**Practical Session: Using appropriate statistical tests**	**Dr.Shaffi**	**Dr.Shaffi**
	1:00 – 3:00	1:00 – 3:00	1:00 – 3:00			
week 15	**24/12/2017**	**20/12/2017**	**21/12/2017**	**Practical Session: How to use SPSS 21.0 for data management?**	**Dr. Shaffi**	**Dr. Shaffi**
	8:00 – 9:00	11:00-12:00	10:00-11:00			
	24/12/2017	**24/12/2017**	**26/12/2017**	**Practical Session: How to use SPSS 21.0for data analysis?**	**Dr. Shaffi**	**Dr. Shaffi**
	10:00-12:00	1:00 – 3:00	9:00-11:00			
	26/12/2017	**26/12/2017**	**27/12/2017**	Data Interpretation	Dr Shaffi Ahmed	Prof.Randa Yousef
	3:00 – 4:00	8:00 – 9:00	8:00 – 9:00			
	27/12/2017	**27/12/2017**	**27/12/2017**	**Practical Session: Data Interpretation**	**Dr.Shaffi**	**Dr.Shaffi**
	8:00-10:00	10:00-12:00	1:00 – 3:00			
	27/12/2017	**26/12/2017**	**28/12/2017**	How to write Results & Discussion?	Dr.Ibrahim Gosadi	Dr. Haifa Wahabi
	10:00-11:00	1:00 – 2:00	8:00 – 9:00			
	27/12/2017	**26/12/2017**	**28/12/2017**	Scientific Writing and report writing	Prof Sultan Meo	Dr Randa Yousef
	11:00-12:00	2:00 – 3:00	9:00-10:00			
	TBD			**FINAL EXAMINATION**		
W 20	**28/01/2018**	**31/01/2018**	**29/01/2018**	**Group Work :Data Management**	**Research Supervisor**	
	1:00 – 4:00	1:00 – 4:00	1:00 – 4:00			
	31/01/2018	**01/02/2018**	**11/02/2018**	**Group Work: Data analysis**	**Research Supervisor**	
	8:00 –10:00	8:00 –10:00	10:00-12:00			
W 22	**14/02/2018**	**14/02/2018**	**22/02/2018**	**Group Work: Data analysis**	**Research Supervisor**	
	9:00-11:00	1:00 – 3:00	1:00 – 3:00			
W 23	**19/02/2018**	**20/02/2018**	**08/03/2018**	**Working with research supervisor writing results & discussion**	**Research Supervisor**	
	1:00 – 3:00	1:00 – 3:00	1:00 – 3:00			
W 25	**05/03/2018**	**06/03/2018**	**13/03/2018**	**Working with research supervisor on Report**	**Research Supervisor**	
	1:00 – 3:00	10:00-12:00	10:00-12:00			
W27	**21/03/2018**	**22/03/2018**	**22/03/2018**	**Working with research supervisor on Report**	**Research Supervisor**	
	8:00 –10:00	1:00 – 3:00	9:00-11:00			
W 29	**04/04/2018**	**05/04/2018**	**02/04/2018**	**Group Work: Making PPT presentation and finalizing report writing**	**Research Supervisor**	
	9:00-11:00	8:00 –10:00	1:00 – 3:00			
W 30	**09/04/2018**	**11/04/2018**	**05/04/2018**	**Group Work: Finalizing report writing and**	**Research Supervisor**	

	2:00 – 4:00	9:00-11:00	1:00 – 3:00	**PPT presentation**	
	15/04/2018 to 19/04/2018			**Submission week for final research report and power point presentation (PPT)**	
				Evaluation by Supervisor (Form B)	
				Research Week	
				Research Presentations	

KEY for HIGHLIGHTED SECTIONS	
No highlight	Lectures
Practical	Practical Sessions
Research Supervisor Session	Research Supervisor Session
Milestones & submissions	Important milestones & submissions during the course

Role of Supervisor and Students

A research supervisor is directly responsible for mentoring the research project of students' right from the inception (deciding about the research topic/question), till the development of final report for submission at the end of course work. The supervisor is to provide counseling on all aspects related to development of research question, objectives, and study design development of proposal, submissions and revisions; that include study objectives, ethical review of proposal, final report, presentation, and progress reports; hence has active involvement in student research project activities and progress. Students have the right to contact supervisor, and an alternate arrangement, in case of leave of absence of supervisor

The supervisor - supervisee relationship needs to be strengthened with mutually accepted expectations on both sides. The supervisor provides quality time, while students are expected to give respect and express maximum learning attitude. This relationship needs to ensure effectiveness, conforming to university policies related to plagiarism and responsible conduct of research. Responsible conduct of research includes: ethical standards, giving credit to students' and others' work, acknowledgements, avoiding plagiarism, obtaining approvals from relevant unit/department heads, and following university policies for collaboration outside KSU.

Selection of Supervisor

Selection of a student research group supervisor must be initiated during the first week of classes and completed at the most by the end of first three weeks of the first semester. Important points for selection of supervisor are: topic of interest, availability, time commitment, and conforming to schedule, and communication methods. Change in topic and supervisor is time constrained and usually results in affecting grades, incomplete work, missing deadlines; hence careful selection of topic and supervisor is important.

Formation of Student Research Groups

Male and Female students will make separate groups. **Five to six students** are recommended to make one group, and can select supervisor on the basis of topic of mutual interest. Student groups are responsible to list their names, IDs, and contact emails on the required Supervisor Agreement Form (SAF) (SAF-attached below) and once they finalize the selection of supervisor to get it signed by the supervisor writing the name, designation, department, and contact email on SAF Form.

King Saud University
College of Medicine CMED 305
Student Research Group Year 3

Supervisor Agreement Form

Please select one of the two options (I or II) from following for indicating selection of supervisor

#	Students' Names (Block Letters)	KSU Student I.D. #	Email Address
1			
2			
3			
4			
5			
6			

I. **This group of students wishes to select the following supervisor (Please fill the following information)**

Full Name of Supervisor	
Department Name	
Email/Phone	

I am willing to supervise this group
Signature of the proposed supervisor:_____

II. **This group of students would like the supervisor to be assigned (please check the box)** ☐

Please submit to Department of Family & Community Medicine by September 26 , 2017

Please note that this is subject to approval by the Dept of Family & Community Medicine

Group Code (will be assigned by coordinators): **_____**

Dr Shaffi Ahmed & Dr.Shatha Ahmed Alduraywish, Coordinators CMED 305

Responsibilities of Student/s

Success of research project will be on drive & ability of students; willingness, availability, and knowledge of supervisor.

A student can enhance his/her performance by the following items:

a) To be prepared ahead of time for lectures, tutorials, assignments, & develop interest
b) Grasp concepts: reads, understands, & applies skills e.g. data management
c) Attends lectures, tutorials, & meetings regularly & help set up a group schedule
d) Develops capacity for independent work, avoids plagiarism, cheating and copying
e) Maintains well organized notes, updates drafts, and works as a team to help group work.
f) Discusses course requirements & deadlines with group and supervisor;
g) Helps the group to set an agenda for each meeting session with research supervisor.
h) Gives notice for raising any specific questions or issues that he/she wishes to raise in meetings (being focussed), and requests for critical feedback.
i) When not satisfied can discuss the working relationship within group and with supervisor.

Responsibilities of Supervisor

Student Research Group (SRG) Supervisor is expected to:

a) Supervise SRG entire research process related to course CMED 305 from the time of inception until the submission of Final Research Report
b) Assist SRG in selecting the pertinent research topic of mutual interest (students & supervisor both)
c) Ensure that the selected research topic is applicable to a larger population *(of public health importance benefitting a considerable segment of population)*.
d) Ensure that research design involves active data collection on new study participants; either based on survey methods, case control study or a follow up in feasible time frame. *(Case reports & small case series are not recommended; this is in reference to six credits allocated to CMED 305 course)*.
e) Supervise the research proposal writing and submission, in general, and for Fast Track Ethical Review Committee for CMED 305 clearance purposes, in specific.
f) Monitor the data collection and management methods by SRG to prevent & avoid any misreporting and mishandling of data.
g) Help students by discussing the results and their interpretation, for writing the results and discussion section, and preparation of final research report.
h) Ensure following the scheduled times for research meetings with SRGs (in case of any change Student Group Leader or course administration is to be consulted confirming any changes in schedule), take attendance of students at each meeting, keep a record of it; evaluate each student and submit progress reports, as recommended by CMED 305 course administration.
i) Deliver student evaluation on time to the course coordinator (i.e. not be sent through students); keeping in mind that delay beyond one week may result in registration of Zero grades for the whole SRG.
j) Work with SRG on preparation of manuscript suitable for consideration for publication (optional for CMED 305 course; can continue beyond course schedule)

Submission Dates and Deadlines

Title of document / Form	Dates
Supervisor Agreement Form	September 28, 2017
Study title, question, objectives, hypothesis, and study design	October 12, 2017
Protocol Submission for Ethical Review Committee	November 26,2017
Evaluation by Supervisor (Form A)	November 26,2017
Final report submission and power point presentation	April 30, 2018
Evaluation by Supervisor (Form B)	April 30,2018

Attendance in lectures, tutorials, and meetings

Students are informed that spontaneous quizzes could be placed during any lecture, tutorial, or meeting time. Hence a prior date for quizzes will not be announced. Any leave of absence will be counted as zero, without an explanation of leave per University Rules & Regulations.

Evaluation of students and course for research

Students will be evaluated by supervisors continuously on their attendance, and progress. The supervisors will communicate the progress to course administration ***twice*** during the course duration, on the prescribed Forms: "A" (at the time of submission of protocol for Ethical Review Committee) and "B" (at the time of final submission of Final Report)

Course administration will take evaluations from Ethical Review Committee on the prescribed Form C, and presentation of power point presentation

Students are strongly recommended to submit Form S for course evaluation, when requested

(All forms, namely: IRB form for protocol submission, Form A, Form B, Form C, and Form S are attached on next pages).

IRB form for protocol submission

Kingdom of Saudi Arabia

KING SAUD UNIVERSITY

College of Medicine

Institutional Review Board

المملكة العربية السعودية
جامعة الملك سعود
كلية الطب
مجلس أخلاقيات البحوث الطبية

نموذج طلب موافقة مجلس أخلاقيات البحوث الطبية

رقم البحث:

عنوان البحث :
الباحث الرئيس والقسم الذي ينتمي إليه :
الباحثون المشاركون والأقسام التي ينتمون إليها :

-

مدة البحث : **شهراً** **الميزانية المقترحة : -**

ملخص البحث (ما بين 150-200 كلمة)

- **مشكلة البحث :-**
- **أهمية البحث :-**
- **أهداف البحث :-**
- **منهجية البحث :-**

توقيع الباحث الرئيس : **التاريخ :**

ملاحظة: لا يقبل أي ملخص ما لم يقدم مطبوعاً باللغة العربية و موقعاً من الباحث الرئيس .

Kingdom of Saudi Arabia

KING SAUD UNIVERSITY

College of Medicine

Institutional Review Board

المملكة العربية السعودية
جامعة الملك سعود
كلية الطب
مجلس أخلاقيات البحوث الطبية

*Please, fill this page if the research proposal is submitted in **English**.*

Research Title:

Summary: (150 – 200 words)

- **Research Problem:**
- **Research Significance:**
- **Research Objectives:**
- **Research Methodology:**

Kingdom of Saudi Arabia

KING SAUD UNIVERSITY

College of Medicine

Institutional Review Board (IRB)

المملكة العربية السعودية
جامعة الملك سعود
كلية الطب
مجلس أخلاقيات البحوث الطبية

مقترح مشروع بحثي
Research Project Proposal

فضلاً، تتم الطباعة إما باللغة العربية أو الإنجليزية *Please, type either in English or Arabic*

أسماء الباحثين * *Investigators Names	*الرتبة العلمية* Academic Title	*الكلية/القسم* College/Department	*التوقيع* Signature

* *الاسم الأول: الباحث الرئيس.*
الاسم الثاني: الباحث المشارك الذي يرشحه الباحث الرئيس ليتولى القيام بالبحث في حال تغيب الباحث الرئيس أو تخليه عن البحث.

* *First name indicates the Principal Investigator (PI).*
Second name is the co-investigator designated by the PI to assume all responsibilities, in case of the absence of the PI.

NOTE: For principal investigator from other college/hospital (outside KKUH) please provide contact details:

Office Tel. No. _____ Department Tel. No. _____

Mobile No. (optional) _____ Email: _____

مشكلة البحث و أهميته

Research Problem and Significance

أهداف البحث

Research Objectives

أدبيات البحث

Literature Review

منهجية البحث

Research Methodology

CONSENT FORM نموذج إقرار

عنوان البحث باللغة العربية
RESEARCH PROJECT TITLE

Principal Investigator: **الباحث الرئيس:**

Co-Investigator(s): **الباحث المشارك:**

SPONSOR: **الداعم:**

You are being asked to participate voluntarily in a Research Study. If you decide to take part in this study, please sign this consent form and return it.

نرجو منك المشاركة في هذه الدراسة البحثية وعند موافقتك بذلك ترجو منك التوقيع على هذه الورقة وإرجاعها إلينا

STUDY PURPOSE: ……. **الغرض من الدراسة:** .....

STUDY PLAN: …… **الهدف من الدراسة:** .....

BENEFITS: The result of this study may not benefit you directly, but in the future with God's will the patients will benefit from the knowledge acquired.

الاستفادة المرجوة من الدراسة: إن الاستفادة من هذه الدراسة قد لا تعود عليك مباشرة ولكن قد تكون لنتائج هذا البحث تأثيرات على معالجة المرضى الآخرين.

SIDE EFFECT: There are no side effects. Your participation in this study does not have any further risks or discomfort to you.

الآثار الجانبية: لا توجد هناك أي أضرار جانبية من هذه الدراسة ومشاركتك لا تسبب أي إزعاج أو مخاطر مستقبلاً

REFUSAL: If you refuse to participate, there will be no penalty or loss of benefits.

عدم الرغبة في المشاركة: إذا رفضت المشاركة في هذه الدراسة فإنك لن تتعرض لأي جزاء أو فقدان للمزايا العلاجية

CONFIDENTALITY: Your participation in this study will be kept confidential. The results of this research may be published, however, your identity will never be revealed.

سرية المعلومات: إن مشاركتك في هذه الدراسة ستكون في غاية السرية. قد يتم نشر النتائج هذا البحث لأغراض أكاديمية ولكن لن يتم الكشف عن هويتك في أي حال من الأحوال.

APPROVAL: I fully understand the information and the consent form.

الموافقة بالمشاركة: استوعبت المعلومات في هذا النموذج, لذا أوافق بالمشاركة في هذه الدراسة. كما أنني لا أمانع من استخدام العينات المتحصل عليها من هذه الدراسة بأن تستخدم في دراسات مستقبلية من قبل الباحثين.
لقد تم شرح هذا النموذج للمتبرع بواسطة أحد الباحثين قبل طلب التوقيع منه.

I sign freely and voluntarily. A copy has been given to me.

أوقع أنا بمحض إرادتي وحريتي وقد تم إعطائي نسخة من الإقرار.

Investigator or Associate:

أسم الباحث أو من ينوب عنه:

Signature:
Date:

التوقيع:
التاريخ:

Patient Name:

أسم المريض:

Signature:
Date:

التوقيع:
التاريخ:

Witness Name:

أسم الشاهد:

Signature:
Date:

التوقيع:
التاريخ:

If you have any further concerns or questions, you can contact Dr. ……. (Tel # ……. Ext. # ……..)

عند الرغبة في أي استفسار عن هذه الدراسة يمكن أن تتصل بالدكتور ..... على تليفون رقم ..... تحويلة .....

المراجع
References

ROLE OF INVESTIGATORS (choose from the following menu, as applicable to each investigator / member in the research group)	
Investigators Names	Brief Description of the Role of Each Investigator

الميزانية التفصيلية
Detailed Budget
(not required for CMED-304 purposes)

(1) *Investigators* — **(1)** الباحثون

التفاصيل Details		المبلغ المطلوب Funds in SR
أسماء الباحثين Names of Investigators	مقدار الجهد بالشهر Effort in months	
(1)		=(شهر)x1200
(2)		=(شهر)x1000
(3)		=(شهر)x1000
(4)		=(شهر)x1000
(5)		=(شهر)x1000
مجموع البند (1) (لا يزيد عن 40% من الميزانية الإجمالية للبحث) *Total(1)*		

Assistants(2) — **(2)** مساعدون

العدد Number	مقدار الجهد بالشهر Effort in months	المبلغ المطلوب Funds in SR
(أ) مساعد باحث ( ) ( ) *a) Research Assistant*		
(ب) فني مختبر ( ) ( ) *b) Lab Technician*		
(ج) طالب جامعي ( ) ( ) *c) University Students*		
(د) إداريون ( ) ( ) *d) Secretaries*		
(هـ) مهارات أخرى( ) ( ) *e) Other professionals*		
مجموع البند(2) *Total (2)*		

**** في حال أن هذا البحث مدعوم يرجى إعطاء التفاصيل التالي:-**
1- الداعم.
2- تفاصيل الميزانية.

**** If the project is funded, please provide:-**

1- Name of Sponsor

2- Details of the budget

(3) Equipments, materials and supplies

(3) مستلزمات

	a) Equipments & (software	*(أ) الأجهزة والبرمجيات*
	(b) Materials	*(ب) المواد*
	(c) Supplies	*(ج) التجهيزات*
	Total (3)	*مجموع البند(3)*

(4)		*Domestic travel*	*الرحلات الداخلية* (4)
(5)		*Computer services*	*خدمات الحاسب الآلي* (5)
(6)		*Other services*	*خدمات أخرى* (6)
		Grand Total	*المجموع الكلي*

الخطة الزمنية للبحث

RESEARCH TIME SCHEDULE *

starting

تاريخ بداية البحث: / / 14 هـ

Date : / / 14 H.

Items البند	التوالي المخطط للأعمال الرئيسة Planned sequence of major tasks	First Semester												Second Semester											
		1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12

Evaluation Form A CMED 305 (Graded by Supervisor)

#	Student Name Group-Code _____	KSU Student ID	Attendance in All scheduled meetings	Can find good literature using search engines	Active in formulation of research question, objectives & ability to develop research hypothesis	Can describe Study design /setting, inclusion & exclusion criteria & target pop	Can help develop study tools, consent, Questionnaire /data form for recording labs or medical records data	Can list data collection procedures to develop a write up as methods	Can state the use of sampling technique & sample size assumptions with justification	Assisted in logical flow of writing or protocol	Overall protocol writing style / Ethical issues/ plagiarism	Overall Responsibility Communicate-on, and ability to meet deadlines	Total
			10	10	10	10	10	10	10	10	10	10	100*
1													
2													
3													
4													
5													
6													

*100 marks: weight-age in total evaluation is 10%

Name & Signature of Supervisor: _____Date: _____

Evaluation Form A: to be kindly submitted on November 26, 2017 to Dr.Shaik Shaffi Ahamed, Course coordinator 305
Department of Family & Community Medicine

Evaluation Form B CMED 305 (Graded by Supervisor)

#	Student Name	KSU Student ID	Attended all meetings	Followed rules for data collection /decision taken in group	Can use the statistical software for data entry, & simple analysis	Can write a plan of analyses ; recoding of variables, and tests of significance	Ability to summarize descriptive statistics and Organization of results in terms of outcomes	can present data in graphs and tables	Can list points in results for discussion and conclusion	Contribution in report writing, & references; avoiding plagiarism	Can help to construct a structured abstract	Overall Recognizes authorship rules/work as a Team including attributes in Form A	Total (a)	Final Total a*0.10
			10	10	10	10	10	10	10	10	10	10	100*	10
1														
2														
3														
4														
5														
6														

*100 marks: weight-age in total evaluation is 10%

Name & Signature of Supervisor: _____Date: _____

Evaluation Form B: to be kindly submitted on April 30, 2018 to Dr.Shaik Shaffi Ahamed, Course coordinator 304 Department of Family & Community Medicine Room

Evaluation Form C for Fast Track Ethical Review Committee (ERC) - CMED 305

Title of Research Project _____

ID #s of Students: 1) _____ 2) _ _____3) _____ 4) _____5) _____6) _____

Suggested items for evaluation using 10 marks for each of the following item checklist.		**Recommendation**	**Score***
1	Background, significance, objectives, hypothesis, are relevant. Methods section provides complete details of study conduct		
2	Consent form/s in English and if needed in Arabic are provided. Waivers of informed consent if applicable explained.		
3	Approval from collaborating agency/institution obtained per university rules (where applicable)		
4	Ethical issues are stated clearly and methods used to address ethical concerns are described		
5	All study tools to be used in study are provided for review (questionnaire, forms for laboratory/Radiology/checklists/other items).		
6	Description of any intervention, test (X ray /body fluid), adverse events, and reporting mechanism with study participants (Studies that involve animal testing and clinical trials need to be approved by Institutional Review Board (IRB) of KSU)		
7	Study Duration is stated explicitly for each activity with time lines chart (Gantt Chart) along with responsible study team members		
8	Describes enrolment method of study participants, # of participants (sample size), and expected time spent by each participant		
9	Inclusion & Exclusion criteria stated clearly for study participants; elaborating in methodology to include or exclude individuals		
10	Confidentiality of study participants is maintained, along with standard of care, with fair selection of community and individuals		
11	Any funding source whether available or not available is stated, describing the resource contribution		

	Form C Continued		
12	Includes statement that this study is designed for the first time during the CMED 304 curriculum time from September 2011.		
13	Any conflict of interest if present is to be reported ; need to be clearly stated even if no conflict of interest is present		
14	Benefits of this study whether on individuals or community; indicating population affected by the expected results.		
15	Any other concern / comment/s (Detailed comments may accompany this checklist)		

*Weight-age in total evaluation is 5%

Any Other Comments

Specific Points for resubmission:

Name & Signature of ERC Committee Chair: _____Date: _____

Collaboration with other departments at KSU

Appropriate approvals from appropriate Department Heads will be required (as needed); given the student group needs support and assistance from other departments/ sections/ laboratory equipment / data from IT department. The SGR supervisor will assist in seeking such approvals, observing the ethical guidelines and standards. Additionally, if students would like to conduct a survey in Primary Health Care Clinics / other clinics (whether at KKUH, KAUH, etc); necessary approvals / guidance from Clinic In-charge will be obtained by students, to pursue relevant approvals with the help of supervisor.

A brief outline of the relevant research proposal, questionnaire and Ethical Review Committee approval will be submitted to the collaborating department.

Collaboration with institutions outside KSU

Given that some research studies require field work outside KSU; may be of multi-center nature or sample size needs to be enhanced in collaboration with a governmental / other body, an official approval for access to study participants or data is mandatory, through special communication / letter from the Vice-Dean for Academic Affairs' Office.

The following steps will facilitate the prompt approval for such outside collaboration.

(1) A **brief outline of the proposal** (1-2 pages), which includes: title, names of students, supervisor's name / title, objectives, methods, potential risk / benefits to human subjects, study duration; expected outcomes.

(2) A **letter (in Arabic) from the Chair of the Dept of Supervisor** to Vice-Dean, Academic Affairs (with copy to supervisor)

(3) The Vice-Dean may either directly approve or send to a relevant committee for approval

(4) The **Vice-Dean officially writes to the potential collaborator** asking for cooperation with the students (e.g. especially for data collection, access to data, etc) with promise of acknowledgement of such cooperation.

Please be advised that students are responsible to compile all documents and follow up with their supervisor, Department's Chair, and Office of the Vice Dean

Such a process needs to be initiated, as early as possible, keeping in mind the timelines or work plan of the study as well as official approvals.

Elements of Research

#	**Writing the Research protocol**
1	Selecting a research topic
2	Formulating a research question
3	Stating the study objectives
4	Formulating research hypotheses
5	Conducting relevant & exhaustive literature search
6	Writing introduction with significance and rationale for the suggested research question
7	Finalizing the study objectives and hypotheses
8	Specifying methodology for
8a.	Study setting, type of study participants, inclusion & exclusion criteria , define cases, controls, other definitions and units for measurements of physical and biological characteristics
8b.	Selecting study design, sampling method, & performing sample size calculation
8c	Designing data collection tools, e.g. Questionnaire, laboratory test (as needed)
8d	Consent form, Ethical Concerns, Institutional policies for collaboration & approvals
#	**Data Collection, Analysis, & Report writing**
9	Data collection (pilot, actual field/ laboratory based)
10	Data management (coding, entry, storage, analysis)
11	Data presentation (tables/graphs)
12	Interpretation of results
13	Discussion writing on findings
14	Final Report write-up using the feedback
15	Preparation of oral / PPT presentation
16	Preparation of a manuscript under supervision of Supervisor

GUIDELINES FOR PROTOCOL DEVELOPMENT

#	**GENERAL REVIEW**	-Each submission will require a signed approval from supervisor. -Cover Page with title, and names of students and supervisor -Contents page sequencing the sections appropriately ; spell checked -Double lined space, in font size 12 for all text , and 14 for headings -Questionnaire/ study tool needs to be attached -Consent form attached (if required for the study)
#	**Section headings of protocol**	
1	Title	-Concise & relevant to study theme, in the context of objectives
2	Introduction And Literature Review	-Recent (last 5 years) knowledge cited/provided (if not available, state justification) -Local, regional and international references to be cited; state if not available -Gaps identified in existing knowledge regarding the study topic/theme -Rationale of study led by the above stated two points
3	Question	Feasible , logical, novel, ethical, and relevant research question
4	Objectives	Specific, measurable, achievable, reliable / relevant, time-bound
5	Hypothesis	To be framed in terms of objectives (null, alternative)
6	Methods	-Study design, setting, and target population to be stated / defined -Setting of study (described in detail to relate how representative is the target population) -Exact methodology for selection of study participants, justifying inclusion and exclusion criteria -Selection of variables to be studied, including variables defined as main outcomes (effects) as well as variables defined as main exposures (causes, risk factors). -Data collection methods / tools: e.g. questionnaire; records; laboratory tests; equipment; measurements like anthropometry, blood pressure etc (as appropriate to study). -Method(s) adopted to minimize potential biases; quality assurance of data at the time of: collection, entry, and storage
7	Ethical Concerns	-Ethical issues considered and maintained throughout the study -Type of informed consent taken (details stated) -Other measures taken to maintain ethical guidelines (as appropriate)
8	Statistical Issues	-Sampling technique described, and sample size calculation stated -Required assumptions and basis of sample size calculation provided -Statistical software used for data management -Plan of analyses according to objectives, study design, and methods -Type of descriptive statistics and distribution of variables stated - Any new variables that could be formed defined and stated e.g. a scoring system, body mass index , % body fat etc.
9	Time Lines	Table :**1)** Tasks, **2)** Time lines in appropriate time unit, **3)** Responsible persons /task
10	References	-Relevant to the topic, cited using Vancouver style*, all references could be verified *Example: Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. N Engl J Med 2002 Jul 25;347(4):284-7.

GUIDELINES FOR PREPARING A RESEARCH REPORT

#		
	General Review	-Each submission will require a signed approval from supervisor. -Cover Page with title, and names of students and supervisor -Contents page sequencing the sections appropriately -Double lined space, in font size 12 for all text , and 14 for headings -Spell checked ; > 3 typological errors in a page may affect marks -Questionnaire/ study tool needs to be attached -Consent form attached (if required for the study)
	Sections stated under protocol review	Title, Introduction & Literature Review, Research Question, Objectives, Hypothesis, Methodology, Ethical Concerns, Statistical Issues, Time plan and References are to be included in final report
	Results	- Number of patients/persons enrolled/considered for enrolment (response rate=number of participants in study /number of sampled participants); how many were excluded due to eligibility criteria; a flow chart can be illustrated -Number of study participants who refused to participate or left during the study period or lost to follow up -Relevant tables and figures appropriately captioned with numbers and / percentages (person, place, time) - Descriptive results ; unadjusted and adjusted results stated (as appropriate)
	Discussion	- Main results discussed in the light of current literature -Concentrate on consistency or lack of consistency of findings with other published work -Explanation of other unusual or any specific outcomes -Clarifying the population/s on whom the results could be generalized -Strengths and Limitations stated pointing towards how any bias could be likely or unlikely and any improvement in methodology recommended e.g. longer follow up of patients, etc. with reasons. Limitations should be discussed in the context of conclusions that will be drawn
	Conclusion & Recommendations	-Relevant and precise based on study results only -Recommendations, if any, based on study results; relevant for any policy level recommendations
	References	-Relevant to the topic, cited using Vancouver style*, and all references could be verified *Example: Halpern SD, Ubel PA, Caplan AL. Solid-organ transplantation in HIV-infected patients. N Engl J Med 2002 Jul 25;347(4):284-7.

College of Medicine
Department of Family & Community Medicine
CMED 305 course

Evaluation Form for PPT. presentation by students(during Research week) by designated evaluators

Title of Presentation: _____

(Please use the scale from 1-5, with 5 being the highest point given for that item)

1.	Introduction was relevant	1	2	3	4	5
2.	Objectives were clearly stated	1	2	3	4	5
3.	Study design, setting , population	1	2	3	4	5
4.	Sampling method & size stated	1	2	3	4	5
5.	Data collection methods explained well	1	2	3	4	5
6.	Main outcome & other variables explained	1	2	3	4	5
7.	Results displayed appropriately	1	2	3	4	5
8.	Conclusion/s based on data	1	2	3	4	5
9.	Recommendations / discussion points	1	2	3	4	5
10.	Ethical issues/Acknowledgements addressed	1	2	3	4	5
11.	Slides were clear/ bulleted	1	2	3	4	5
12.	Clarity of presentation	1	2	3	4	5
13.	Completed in time	1	2	3	4	5
14.	Handling of questions	1	2	3	4	5
15.	Overall presentation style	1	2	3	4	5

Evaluator's Name/Signature:_____

Course Administration

The course consists of six credit hours and curriculum time is distributed as one third each for lectures, practical sessions, and research group meetings.

All communication from students and supervisors is to be made to coordinators only; office Staff at the following personnel at the contact address as following.

All submissions by students will be done at the Department of Family & Community Medicine to Ms.Sharmina, secretary to CMED 305 Course.

Supervisors need to send evaluations to Course Coordinators, through a porter or secured campus mail; or email (evaluation forms not to be sent by students).:

Name	Email	Ext Phone Number
Coordinators		
Dr Shaffi Ahmed	shaffi786@yahoo.com ; shaffiahamed786@gmail.com	71544
Dr.Shatha Ahmed Alduraywish	s.alduraywish@gmail.com	71653
Administrative staff		
Ms.Sharmeena Administrative Assistant	**shatta@ksu.edu.sa**	92768
Mr. Badar Al-Rowaili: Administrative Assistant	fcm@ksu.edu.sa	70836