Course Title: MLT 694 Research Methods

Course Director: Dr. Ahmed Mirza, Ph.D., MT (ASCP)

Credit: 2 Hours

#### Textbooks:

# Required:

 Designing Clinical Research. Hulley, Stephen, B., et al. Lippincott Williams & Wilkins, 3<sup>rd</sup> ed. ISBN-10: 0-7817-8210-4, ISBN-13:978-0-7817-8210-4

#### Recommended:

- The Research Methods Knowledge Base. Trochim, William M.K.
   Donnelly, James P. CENGAGE Learning. 2008. ISBN 1592602908
- Introduction to Research. Elizabeth DePoy & Laura Gitlin. Elsevier Mosbey. 3rd Ed. ISBN-13:978-0-323-02853-0

### **Course Description:**

This course is composed of two sections, the first section is composed of several preparatory session needed to bring students up to the required level to endeavor on medical research projects, while the second section of the course is designed to discuss the different components and terminology of research as well as various research models ranging from the highly quantitative to broad qualitative methods. The course will provide a practical approach to research planning through the logical sequence of developing a research proposal pertaining to the research interests of individual students. Formulation of research questions, hypotheses, literature search techniques, ethical issues, and the writing of the research proposal/final research report and the dissemination of research findings will be discussed. This course is designed to provide the first-time researcher with the skills to undertake research and to write up proposals and final reports in areas of their choice. It is highly recommended that students have a research topic of interest before taking this course

### **Learning outcomes:**

At the completion of this course, the participant will be able to:

- 1. Compile articles to produce a strong literature review in support of a proposed hypothesis.
- 2. Formulate and manipulate several hypotheses pertaining to the topic of interest according to the different research designs.
- 3. Choose the appropriate components according to sound research design based on research topic of choice.
- 4. Construct the different components of a research proposal
- 5. Compose and present a research project proposal in compliance with course and departmental standards.

#### **Milestones:**

- 1. Formulation of a research question.
- 2. Initiation of a proposal literature review
- 3. Iteration of research hypothesis(es)
- 4. Research design and formulation of the proposal components
- 5. Completion of the ethics certificates
- 6. Submission of a written proposal

### Format:

Students will be assigned readings from the text book, suggested book and/or outside material. There are weekly written assignments dealing with the various aspects of research, data analysis and the students' development of their own proposals.

Homework is divided into exercises covering lecture material, and assignments for developing a proposal. All homework is due on date of the following lecture. Late homework will only be accepted with a valid excuse determine by the course director, and only if the course instructor is notified *prior* to the assigned due date. Performance evaluation will be in the form of quizzes and a final comprehensive exam. Finally, students are to defend their proposal in front of their peers and faculty members.

This course has a Blackboard shell, which will be fully utilized for assignment posting and submissions, proposal components submissions, discussion and all class related communications. Students are expected to check the site frequently and are responsible for all materials and messages contained on it. Furthermore, students, by program policy, are expected to frequently check their E-mail, preferably KAU email, which will serve as a backup communication system if the primary service is down. Attendance at all sessions is required for successful completion of the course. The course instructors have no obligation to make up course materials missed.

#### **Evaluation:**

Grades will be derived from the following

4 Quizzes	20%
Ethics certificates	5%
Assignments	25%
Written proposal	10%
Oral presentation	10%
Comprehensive final	30%

# **Tentative Weekly Lecture Schedule**

Week 1 Prep Unit i	Anatomy of the Scientific Paper (TS)
Weeks 2 & 3	Literature Review workshop (NE)
Prep Unit ii Weeks 4	Online search PubMed-MeSH and other databases (AM/HH)
Prep Unit iii	Offiline search i ubivied-ivies i and other databases (Aivi/i ii i)
Weeks 5	Reading the scientific paper (workshop format) (AM/HH)
Prep Unit iv	
Weeks 6	Endnotes workshop (RF)
Prep Unit v	
Week 7&8	Scientific method
Unit I a&b	Research component
Research Basics	FINER
	The Hypothesis Introduction to the P-value
	Sampling
	Measurements
	(AM)
	Quiz – Unit la (week 8)
Week 9	Cohort Study
Unit II	Cross-Sectional Studies
Basic Study	Case-Control Studies
Designs	Enhancing Causal Inference
	(AM)
10/ 1 40	Quiz – Unit Ib
Weeks 10	Randomized Blinded Trail
Unit III	Alternative trial Design
Advanced Study Designs	Designing Studies for Medical Tests (AM)
Designs	Quiz – Unit II
Weeks 11	Qualitative Design– Guest lecturer
Unit IV	Surveys – Guest lecture
	(RM)
	Quiz – Unit III
Weeks 12	Effective Power Point Presentations (AM)
10/ 10/	Quiz – Unit IV
Weeks 13	Addressing Ethical Issues in Research (DH)
Prep Unit viii	Drocontations of proposals and criticals (Part I)
Week 14 Mock Proposals	Presentations of proposals and critique (Part I) (AM)
Week 15	Presentations of proposals and critique (Part 2)
Mock Proposals	(AM)
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<u>Assignment, exercises, and written article reviews will be assigned by the course director as the course progresses</u>

# Preparatory sessions goals and learning outcomes

These preparatory units are designed to complete possible missing knowledge in students of the MS program. These units are predominantly based on workshop-style sessions to give hands-on practice to participants. Assignments might be assigned per the discretion of the instructor for extra learning. No exams will be given to assess these preparation units; exams will be used to assess the research methods core units.

# Preparatory Unit 0: Plagiarism and Paraphrasing Dr. Ahmed Mirza

#### Goal:

The goal of this unit is to familiarize the student with acts of plagiarism, and how to avoid it in paraphrasing

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Identify all acts of academic plagiarism
- 2. Use proper citation when necessary
- 3. Methodically employ specific steps for proper paraphrasing
- 4. Methodically employ specific steps for proper summarization

# Preparatory Unit i: The Anatomy of the Scientific Paper Guest Lecturer: Dr. Thoraia Shinawi

#### Goal:

The goal of this unit is to familiarize the students with the IMRAD structure of scientific research papers

### **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Describe and identify the basic sections of the typical IMRAD article
- 2. Classify the content type of each section
- 3. Discuss the format and purpose of abstracts
- 4. Write an abstract
- 5. Discuss the relevance of impact factor when evaluating a journal publication
- 6. Discuss the relevance of "Peer review" and "conflicts of interest" when evaluating a paper

# Preparatory Unit ii: Literature Review Workshop Guest Lecturer: Dr. Noora Eid

#### Goal:

The goal of this unit is to educate students with skills needed for initiating an organized literature review

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Create an initial structure of the literature review
- 2. Use research skills in finding relevant key papers
- 3. Build knowledge and critical appraisal of a topic of interest
- 4. Write the literature review for publication use

Preparatory Unit iii: Efficient PubMed Search

Guest Lecturer: Dr. Ahmed Mirza

#### Goal:

The goal of this unit is to empower students with the skills needed for effective and fruitful literature search using PubMed

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Utilize the PICO approach for searching a topic
- 2. Use MeSH to search the literature for a topic
- 3. Employ Boolean operators to narrow down a search in PubMed
- 4. Use "truncation", "quotation", and "parentheses" to aid in literature search in PubMed
- 5. Use the "advanced" search option in PubMed
- 6. Employ filters to refine literature search
- 7. Retrieve articles from the Saudi Digital Library

# Preparatory Unit iv: Reading/understanding the scientific paper (workshop) Guest Lecturer: Dr. Ahmed Mirza/Hani Alhadrami

#### Goal:

The goal of this workshop unit is to train students on breaking down the knowledge of the paper to specific keywords

#### **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Evaluate articles through identifying keywords and sections
- 2. Articulate the main points of paragraphs
- 3. Summarize main objectives of paragraphs in few words

Preparatory Unit v: Endnotes
Guest Lecturer: Dr. Ra'id Filimban

#### Goal:

The goal of this unit is to train students on the use of Endnotes or similar programs

#### **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Explain the overall method of referencing in Endnotes or other programs
- 2. Use Endnotes for proper citation

# Preparatory Unit vii: Effective presentation, Putting the "Power" in your PowerPoint

Guest Lecturer: Dr. Ahmed Mirza

#### Goal:

The goal of this unit is to empower students with the skills needed for developing and delivering an informative and enjoyable presentation.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Outline the components of a presentation
- 2. Professionally present by
  - Communicating effectively
  - Gaining confidence
  - Engaging the audience
  - Citing appropriate references
- 3. Work well as a team

# Preparatory Unit viii: Ethical Considerations in Research Guest Lecturer: Dr. Dima Hussein

#### Goal:

The goal of this unit is to familiarize the student proper procedure to conduct ethical research.

#### **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Differentiate ethical from unethical
- 2. Define informed consent
- 3. Discuss the ethical considerations of consent
- 4. Discuss why "Good science & good animal care go hand-in-hand"
- 5. Explain the difference between animal rights and animal welfare?
- 6. Define and Discuss the application of the 3 R's
- 7. Discuss how ethical approval procedures can promote animal welfare (use example)
- 8. Describe potential ethical problems, and unethical behavior, that may occur at different stages of the research process
- 9. Define scientific misconduct and fraud, and discuss the potential harm it can cause

# **Assignment Objective:**

Upon the completion of this certificate the student will understand:

1. The events that lead to the development of universal research ethics

- 2. Why informed consent is necessary and the guidelines that brought it about
- 3. What is involved in taking informed consent from a potential study participant and the information they should be provided with
- 4. Who is, and is not, eligible to sign a consent form
- 5. Language that should not be used when asking an individual to enrol in a study
- 6. The options that are available for non-paper-based communities
- 7. Points to be considered when taking consent

# **Assignment**

Students must complete the "Introduction to informed consent" certificate at the Global Health Training Centre website.

(Global Health Training Centre. Retrieved on Jan 29, 2018 from https://globalhealthtrainingcentre.tghn.org/introduction-informed-consent/)

# Core units goals, learning outcomes, outline, readings, and sssessments

# Unit I-a: Introduction to Research and its Components

#### Goal:

The goal of this unit is to familiarize the student with common terminology, ideas and basic principles of research.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Express the importance of research
- 2. Arrange components of a research protocol
- 3. Distinguish amongst the following:
  - a. Philosophy, epistemology, and methodology
  - b. Internal and external validity
  - c. Ecological and exceptional fallacies
  - d. Dependent and independent variables
- 4. Classify research or its components under the following:
  - a. Experimental, quasi-experimental, and non-experimental designs
  - b. Descriptive, relational, and causal studies
  - c. Time in research: longitudinal retrospective/prospective, crosssectional and cohort
  - d. Inductive and deductive reasoning
  - e. Null and alternative hypotheses
  - f. One-sided and two-sided alternative hypotheses
  - g. Type I and type II errors
- 5. Employ Scientific method to solve simple questions
- 6. Draft a research question according the FINER elements of research
- 7. Conduct efficient literature searches employing available resources
- 8. Assess current knowledge
- 9. Draft primary, secondary alternative and null hypotheses
- 10. Understand P-value and assign proper  $\alpha$ ,  $\beta$ , and power values

- 1. Why Research
  - a) Classical research lab
  - b) Population research trials
  - c) Translational research (T1 and T2)
- 2. Sources of knowledge
  - a) Philosophy
  - b) Epistemology and methodology
  - c) Deductive and inductive reasoning
  - d) Empiricism and rationalism
- 3. Definitions
  - a) Internal and external validity
  - b) Ecological and exceptional fallacies
  - c) Dependent and independent variables

- d) Effect size and power
- 4. Research components
  - a) Research question
  - b) Background and significance
  - c) Design
  - d) Subjects
  - e) Variables
  - f) Statistics
  - g) Analysis
  - h) Reports
- 5. Types of research
  - a) Experimental
  - b) Quasi experimental
  - c) Non-experimental
  - d) Blinded
  - e) Descriptive
  - f) Longitudinal
  - g) Relational
  - h) Causal
- 6. Time in research
  - a) One-time study
  - b) Longitudinal
    - i. Prospective
    - ii. Retrospective
- 7. Scientific method steps
- 8. The research question
  - a) Where do research questions come from?
    - i. Literature
    - ii. Being Alert
    - iii. Imagination
    - iv. Mentor
  - b) FINER characteristics of good research questions
  - c) Primary and secondary questions
- 9. The Aims of the study
- 10. Literature review
  - a) Why?
  - b) Being organized is the key for less headaches
  - c) Resources
- 11. The Hypothesis
  - a) The Good Hypothesis
  - b) Types of hypothesis
    - i. Null
    - ii. Alternative
      - (1)One-sided
      - (2)Two-sided
    - iii. Secondary hypotheses
    - iv. Multiple and post-hoc hypotheses

- c) Statistical error in conclusion
  - i. Type I
  - ii. Type II
- d) P-value
- e) Assigning proper  $\alpha$ ,  $\beta$  and power

Hulley 1, 2 and 5 Trochim 1

#### **Evaluation:**

- 1. Quiz Unit I-a
- 2. Assignment

# **Assignment Objective:**

Upon the completion of this assignment the student will formulate a research question following the guidelines of a FINER research.

**Assignment 1**: Think about the topic of a thesis/project and formulate a research question using the material we covered thus far and in chapter 2 of the Hulley book. Your research question should be one small paragraph focused on one primary inquiry. Nothing is wrong if you want to ask secondary questions, but it might get complicated. Then write a brief discussion (a page) of your question(s) adherence to the FINER guidelines of research.

So again, two requirements that should fit on a maximum of two pages, single spaced:

- 1. State a research question (one paragraph)
- 2. State The type of research
- 3. How does it follow the FINER characteristics (five paragraphs)?

# Unit I-b: Sampling and measurements

#### Goal:

The goal of this unit is to familiarize the student with different sampling schemes, measurements scales, accuracy and precision. Furthermore, the unit will briefly introduce the student to statistical tools and their applications in estimating sample size and data analysis.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Select appropriate inclusion and exclusion criteria to best fit the research design
- 2. Utilize the following methods to sample a population to achieve good external validity
  - a. Probability sampling
    - i. Simple random
    - ii.Systematic
    - iii. Stratified random
    - iv. Cluster
  - b. Non-probability sampling
    - i. Convenience
    - ii.Consecutive
    - iii. Judgmental
- 3. Distinguish the data amongst the following measurement scales
  - a. Continuous (interval, ratio)
  - b. Categorical (dichotomous, ordinal, nominal)
- 4. Categorize the data as Parametric or non-parametric

- 1. Selection criteria
  - a) Inclusion criteria
  - b) Exclusion criteria
  - c) Clinical vs. Community population
- 2. Sampling
  - a) Probability sampling
    - i. Simple random sampling
    - ii. Systematic sampling
    - iii. Stratified random sampling
    - iv. Cluster sampling
    - v. Multi-stage sampling
  - b) Non-probability sampling
    - i. Convenience sampling
    - ii. Purposive sampling
- 3. Recruitment
- 4. Measurements scale and Variables
  - a) Continuous

- i. Intervals
- ii. Ratios
- b) Categorical
  - i. Nominal
  - ii. Dichotomous
  - iii. Consecutive
  - iv. Ordinal
  - v. Judgmental
- 5. Precision
  - a) Sources of random error
  - b) Assessing precision
  - c) Enhancing precision
- 6. Accuracy
  - a) Sources of systematic error
  - b) Assessing accuracy
  - c) Enhancing accuracy
  - d) Validity
    - i. Content validity
    - ii. Construct validity
    - iii. Criterion validity
- 7. Parametric vs. non-parametric data
  - a) Descriptive studies
    - i. Continuous variables
    - ii. Dichotomous variables
    - iii. Non-continuous variables

Hulley 3, 4 & 6

#### **Evaluation:**

- 1. Quiz Unit I-b
- 2. Assignment

### **Assignment Objective:**

Upon the completion of this assignment the student will state a null hypothesis and suggest an alternative hypothesis according to a research question. The student will also decide on the type of expected collected data and sampling method to be used.

**Assignment 2:** Create the following elements of your research in full details:

- 1. State the appropriate null hypothesis pertaining to your research question and the alternative hypothesis opposing it.
- 2. Identify the variables and state their type (para- vs. non-parametric) and explain why

# Unit II: Basic Study Designs

#### Goal:

The goal of this unit is to familiarize the student with different study designs, their advantages and disadvantages, and methods to improve their efficacy. Furthermore, the unit will discuss the methods to design better medical tests.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Outline the protocol of the following study design and explain their strengths and weaknesses:
  - a) Prospective and retrospective cohort studies
  - b) Nested case control and nested case-cohort studies
  - c) Cross-sectional studies
  - d) Case-control studies and case-crossover studies
- 2. Detect spurious association (chance and bias)
- 3. Detect real associations (confounders, effect-cause)
- 4. Utilize the following methods to reduce confounders:
  - a) Specification
  - b) Matching
  - c) Opportunistic
  - d) Stratification
  - e) Adjustment
  - f) Propensity scores

- 1. Prospective cohort study design
  - a) Structure
  - b) Strength and weaknesses
- 2. Retrospective cohort study design
  - a) Structure
  - b) Strength and weaknesses
- 3. Multiple-cohort study design
  - a) Structure
  - b) Strength and weaknesses
- 4. Cross-sectional study design
  - a) Structure
  - b) Strength and weaknesses
- 5. Case-control study design
  - a) Structure
  - b) Strength and weaknesses
  - c) Bias
    - i. Controlling sampling bias
    - ii. Controlling differential measurement bias
- 6. Nested case-control and case-cohort study design
  - a) Structure
  - b) Strength and weaknesses

- 7. case-crossover study design
  - a) Structure
  - b) Strength and weaknesses
- 8. Associations
  - a) Spurious association
    - i. Ruling out chance
    - ii. Ruling out bias
  - b) Real association
    - i. Effect cause
    - ii. Confounding
- 9. Dealing with confounders
  - a) Design phase
    - i. Specification
    - ii. Matching
    - iii. Opportunistic studies
  - b) Analysis phase
    - i. Stratification
    - ii. Adjustments
    - iii. Propensity scores
- 10. Evidence favoring causality

Hulley 7, 8 & 9

#### **Evaluation:**

- 1. Quiz Unit II
- 2. Assignment

# **Assignment Objective:**

Upon the completion of this assignment, the student will be able to:

1. identify the main research components within articles pertaining to their research question.

# **Assignment 3:**

Using the skills you have gained thus far in the course, conduct a literature review of 5 research (not review) articles pertaining your research question and identify their main research components listed below:

- 1. The research question or the gap of knowledge
- 2. Research type
- 3. Null and alternative hypotheses.1- or 2-sided
- 4. Aims of the study
- 5. Variables
- 6. Sampling methods (state the inclusion and exclusion criteria if specified)
- 7. Research design

# Unit III: Advanced Study Designs

#### Goal:

The goal of this unit is to familiarize the student with other alternative to the basic ones discussed in the previous unit. Furthermore, the unit will discuss the methods to design better medical tests.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Outline the proper way to conduct the following study designs
  - a) Randomized blinded trial
  - b) Factorial design
  - c) Cluster randomized design
  - d) Equivalence trial
  - e) Non-randomized design
  - f) Crossover design
  - g) Clinical trials
- 2. Determine the usefulness of a medical test by properly calculating:
  - a) Sensitivity and specificity
  - b) Positive and negative predictive values
  - c) ROC curves

- 1. Designing randomized blinded trial
  - a) Selecting intervention
  - b) Selecting control
  - c) Selecting outcome measurements
  - d) Selecting participants
- 2. Measuring baseline variables
- 3. Randomizing and blinding
  - a) Random assignments
    - i. Blocked randomization
    - ii. Stratified blocked randomization
    - iii. Matched pairs randomization
  - b) Blinding
- 4. Factorial design
  - a) The basic  $2 \times 2$
  - b) Factorial design variations
  - c) Cluster randomization
- 5. Nonrandomized between-group design
- 6. Within-group design
- 7. Pilot clinical trials
- 8. Conducting clinical trials
  - a) Follow-up
  - b) Adjudicating outcome
  - c) Monitoring
  - d) Analyzing the results

- 9. Designing studies for medical tests
  - a) General issues
    - i. Gold standard
    - ii. Spectrum of severity of diseases
    - iii. Other sources of variations
    - iv. Blinding
    - v. Costs vs. charges
- 10. Test reproducibility
- 11. Test accuracy
  - a) Sensitivity and specificity
  - b) Positive and negative predictive values
  - c) Receiver operating characteristics (ROC) curves

Hulley 10, 11 & 12

#### **Evaluation:**

- 1. Quiz Unit 4
- 2. Assignment 3-continued

# **Assignment Objective:**

The objective of this homework is to conduct the start of a mini-literature review to support, and make relevant your research effort to answer your question. Upon reading scientific articles the student will be able to:

- 1. Identify the main research components within articles pertaining to their research question.
- 2. Summarize the approach and conclusion
- 3. Critique the conclusion of the author(s) according its relevance to his/her research interest

#### **Assignment 4:**

- As before in assignment 3, conduct a literature review of 5 EXTRA
  research (not review) articles pertaining your research question, and
  identify their main research components as before considering the
  alternative research design we just covered. You might have to reexamine the first five articles.
- 2. In a short summary (not exceeding one page) answer the following questions about each of the **ten** articles:
  - a. What was the overall approach taken to solve the research question?
  - b. What do you conclude from the paper?
  - c. **Discuss** whither the author make a strong point (*i.e.*, do you buy it? Why or why not?)
  - d. **Discuss** how would it relate to your research?

Obviously the first few questions will be answered in few lines. The last two questions (the **Discuss** ones) should make the bulk of your homework.

# Unit IV: Qualitative Designs

#### Goal:

The goal of this unit is to familiarize the student with different qualitative research designs such as meta-analysis and surveys, their advantages and disadvantages, and methods to improve their efficacy.

# **Learning Outcomes:**

At the completion of this unit, the participant will be able to:

- 1. Recognize the different genera of qualitative research
- 2. Recommend the most useful qualitative measure per research question
- 3. Recognize and explain characteristics of a good qualitative research
- 4. Explain the advantages and disadvantages of utilizing existing databases
- 5. Suggest the use of previous data for secondary data analysis
- 6. Suggest the use of previous data for ancillary studies
- 7. Outline the elements of a good systematic review in meta-analysis
- 8. Identify the different types of surveys, their advantages and disadvantages
  - a. Questionnaires
  - b. Interviews
- 9. Identify the different types of questions in a questionnaire
  - a. Open-ended questions
  - b. Close-ended questions
- 10. Outline characteristics of a good questionnaire instrument
  - a. Formatting
  - b. Wording
  - c. Time frame and placement.
  - d. Appropriate scaling
- 11. Utilize and design a survey using available recourses

- 1. Key terms
  - a) Ethnography
  - b) Phenomenology
  - c) Field research
  - d) Grounded theory
- 2. Qualitative measures
  - a) When?
  - b) Qualitative vs. quantitative data (flexibility)
  - c) Qualitative measure s and observations
    - i. Participant observation
    - ii. Direct observation.
    - iii. Structured vs. unstructured observation
    - iv. Focus groups
    - v. Evaluation research
  - d) The quality of qualitative research
  - e) Unobtrusive measurements

- 3. Databases
  - a) Advantages and disadvantages of using databases
  - b) Secondary data analysis
  - c) Ancillary studies
- 4. Systematic review (meta-analysis) and elements of good meta-analyses
  - a) Research question
  - b) Complete studies
  - c) Inclusion and exclusion criteria
  - d) Eligible studies
  - e) Presentation
  - f) Stats
  - g) Publication bias
- 5. Surveys
  - a) Designing questionnaires
    - i. Open-ended questions
    - ii. Closed-ended questions
    - iii. Formatting
    - iv. Wording
    - v. Time frame
    - vi. Scaling
      - (1) Thurstone
      - (2) Likert
      - (3) Guttman
  - b) Interviews

Hulley 13 & 15 Trochim 4, 5, 6 & 8

# **Evaluation:**

1. Quiz – Unit III

**Assignment Objective:** The student will devise a research plan in which he/she will:

- Formulate a more educated study question post-literature review and compare it to a previously stated question
- 2- Generate an alternative hypothesis and state the null
- 3- Plan out specific and well-defined aims
- 4- Assemble the subjects and controls utilizing defined exclusion and inclusion criteria

# Assignment 5:

Develop the following regarding your research project:

1) A research question. We have done this before, but to some this question might have changed, to others the question will be better written after the lit review you just conducted. For example, can drug "x" reduce the symptom(s) of disease "y"? (10 pts)

- 2) The hypothesis. This should be a one sentence answer to your question. (10 pts)
- 3) Aims. These are the specific steps take to prove your hypothesis. For example, aim 1: establish a base line for the symptom by doing "z" blood test. Aim 2: use a variety of "x" drug concentrations and placebo for one month to show effectiveness of drug "x" against disease "y". It is very important that you know what you need to do EXACTLY, so ask for help from your research advisor. Keep in mind that it is possible to have one aim in your study. (20 pts)
- 4) Study design (cross-sectional, case-control, clinical-trial, etc). Give a very short reason why you chose this design specifically. (10 pts)
- 5) Variables: dependent and independent (aka, predictor and outcomes). The independent variable is that which you will control (concentration of "x" drug) to see its effects on the dependent variable, which you are interested in studying ("z" symptoms, or blood test as a surrogate marker) (10 pts)
- 6) Subjects and controls. Describe the type of samples (subjects & controls) according to:
  - a. Inclusion and exclusion criteria (10 pts)
  - b. Methods of selecting the control (10 pts)
  - c. Number of samples and controls needed for good stats (10 pts)
- 7) Possible methodology to be used. This is not the study design in question 4, but more specific and detailed. How are you going to conduct the research? This section might be difficult, but can be easily completed by emailing your advisors for the possible procedures to be done. The procedures need not to be explained, just list them. If you don't know what methods you are about to use, then you are in trouble (10 pts)

As you can see the assignment is not very long, I am just asking for details in a **bullet form**. You will be graded on the provision of the above information. PLEASE REFRAIN FROM USNING LONG PARAGRAPHS OF EVERYTHING SQUEEZED TOGETHER. Please be organized.

# **Final Written Mini-Proposal**

Write a mini-proposal for your research topic following the KAU MS proposal guidelines. The proposal should come out to be between 14-20 pages (DOUBLE SPACED)

# Guidelines to writing a proposal

You need to show the following clear sections:

#### Introduction

A very brief explanation of why you want to do what you propose to do, brief statement of the problem, how this research might fix it, and it ends with the research question. The introduction is a summary and should be written last and after the literature review has been written (ONE PAGE) (5 Pts)

#### Literature review

(Keep in mind that both the literature review and the methodology sections can be sectioned under further sub-headers.)

The literature review should include the nine articles previously summarized plus another nine if possible; a minimum of **fifteen (15)** articles. Break down the literature to sub-categories that will make the audience better understand your reasoning behind your study. The benefit of sub-headers is that it focuses the attention of readers early on the main point of the section, rather than letting them do it on their own and miss the point. So, from the get-go, the reader will know that the specific part he/she is reading will be talking about (e.g., biomarkers of cancer) and so will focus their mind on that specific subject. Some example, brief anatomy/physiology of the disease, risk factors, assessment methods, treatments, surgical procedure, recent work covering (or lack of covering) the problem, etc. (This part should make up the bulk of your paper) (30 Pts). The literature review should tell a story leading to a gap of knowledge that can be answered by a specific research question.

#### Relevance of the Research

This section is usually a part of the literature review (the FINER assignment could be of help here). However, to accommodate the requirements of the proposal submitted to the Deanship of Graduate Studies and Research, it will be written as a separate section.

# **Hypothesis**

The hypothesis will answer the research question above. (5 Pts)

#### Aims

A list in bullet form of the phases (each could be an experiment of several experiments) you plan to do. (Keep it minimal) (5 Pts)

#### Methodology

Same thing as the lit review goes for methodology, but now you include what I asked for in assignment 3 (you can elaborate a bit more if you like.)

- 1. Study design (e.g., retrospective cohort) (5 Pts)
- 2. Selection of the subjects (sampling; age, sex, demographics) (5 Pts)
- 3. Selection of controls (none or positive and negative; this is not just limited to case-control studies obviously) (5 Pts)
- 4. The venue of the study (lab, hospital, city, state, planet...) (5 Pts)
- 5. Time line and cost (rough estimations I know you are new to this) (5 Pts)
- 6. Analysis/stats (how do you approach looking at predictors vs. outcomes) (5 Pts)
- 7. The strength and drawbacks of using this design (AKA limitations) (10 Pts)

### References

Use which ever method of accepted citing. Just be consistent. Look at these links (20 Pts)

#### **Publications**

http://www.ncbi.nlm.nih.gov/bookshelf/br.fcgi?book=citmed

Citing unpublished material

http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=citmed.part.1324

http://www.yale.edu/bass/writing/sources/kinds/miscellaneous/unpublished.html