# Writing an Introduction of a research protocol

Dr Ali Al-hazmi

# By the end of this session, you will be able to:

- Understand what is research protocol ?
- Identify the components of a research protocol
- Understand the importance of research protocol
- Able to write a research protocol introduction

# **Research Protocol**

- A formal written record that one prepares BEFORE research fieldwork is undertaken
- provide a clearly and plainly provides an overview of a proposed study

satisfy an organization's guidelines for protecting the safety of human or animal subjects who might be adversely impacted by the research.

## **Research Protocol**

Research protocols are typically submitted to Institutional Review Boards (IRBs) within universities and research centres. Components of A Research Protocol

#### 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** 

Please, type either in English or Arabic

فضلاً، تتم الطباعة إما باللغة العربية أو الإنجليزية

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	التوقيع	الكلية/القسم	الرتبة العلمية	أسماء الباحثين
	Signature	College/Department	Academic Title	*Investigators Names
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				* الاسم الأول: الباحث الرئيس.

الاسم الثاني: الباحث المشارك الله ييشحه 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:

Please provide contact details where we can contact you in case of incomplete/missing, documents.

Office Tel. No.

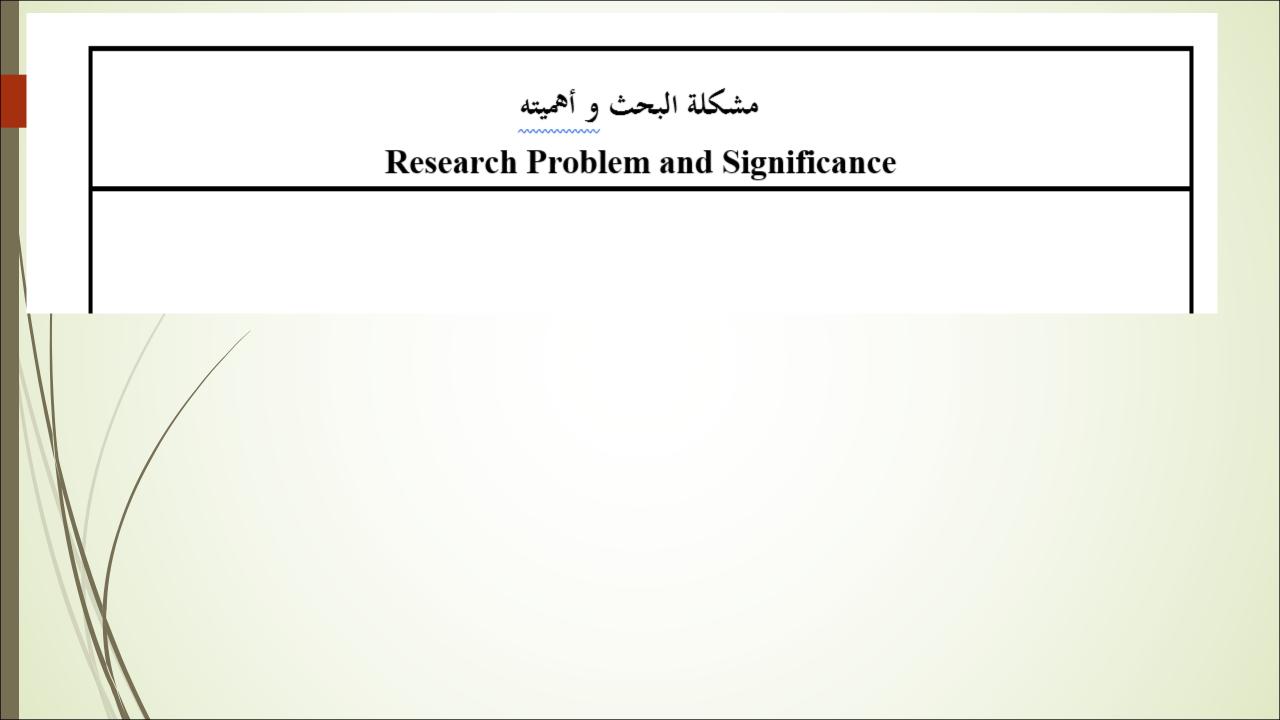
Department Tel. No.

Mobile No. (optional)

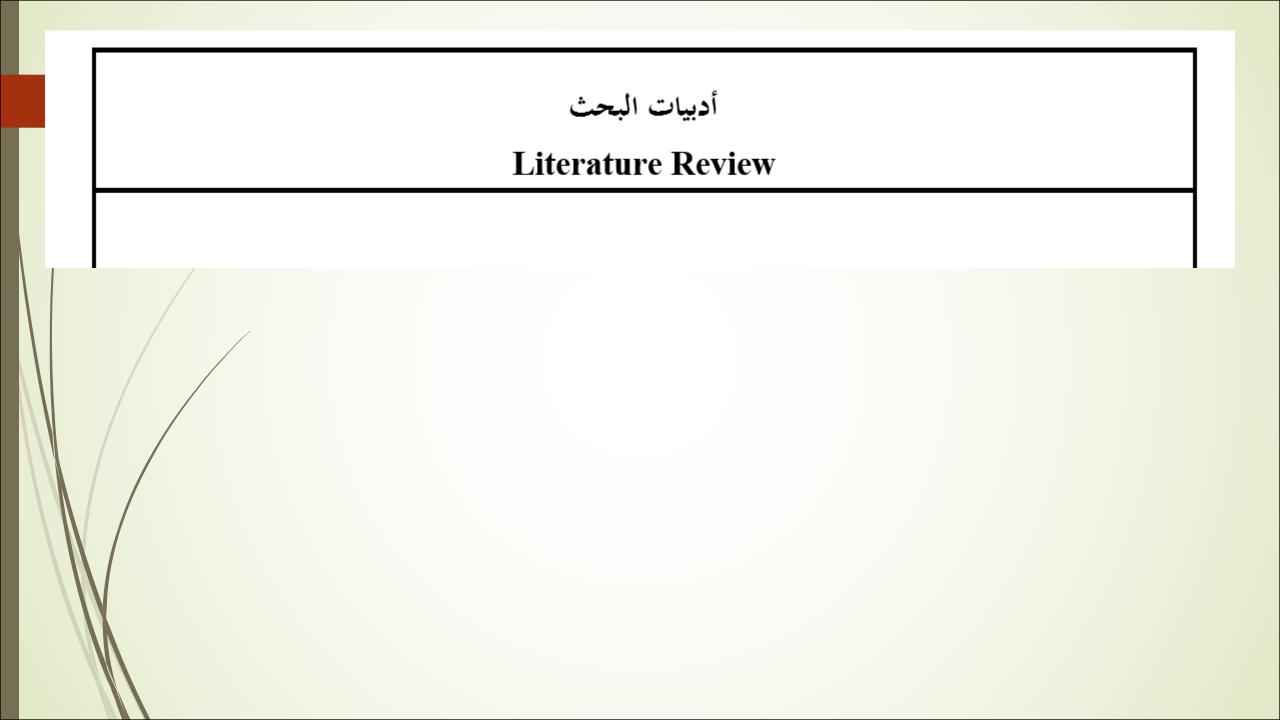
Email:

Kingdom of Saudi Arabia KING SAUD UNIVERSITY College of Medicine Institutional Review Board	المملكة العربية السعودية جامعة المللك سعود كلية الطب مجلس أخلاقيات البحوث الطبية
رقيات البحوث الطبية	نموذج طلب موافقة مجلس أخا رقم البحث:
الميزانية المقترحة :	عنوان البحث : الباحث الرئيس والقسم الذي ينتمي إليه : الباحثون المشاركون والأقسام التي ينتمون إليها : مدة البحث : مدة البحس :
<b>Summary:</b> (150 – 200 words)	ملخص البحث (ما بين ١٥٠–٢٠٠ كلمة)
Research Title:	البحث: 🗇 عنوان البحث:
Research Problem:	البحث: 🗇 مشكلة البحث:
Research Significance:	الهمية البحث: 🍲
Research Objectives:	اهداف البحث:
Research Methodology:	البحث: المجية البحث:
:	نوقيع الباحث الرئيس : التاريخ

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







منهجية البحث

Research Methodology

Study Design: (تصميم الدراسة)

(مدة الدراسة) Study Duration

(إعداد الدراسة) :Study Setting

Target Population/Sample Size: (السكان المستهدفين / حجم العينة)

Inclusion Criteria: (معايير الاشتمال)

Exclusion Criteria: (معايير الاستبعاد)

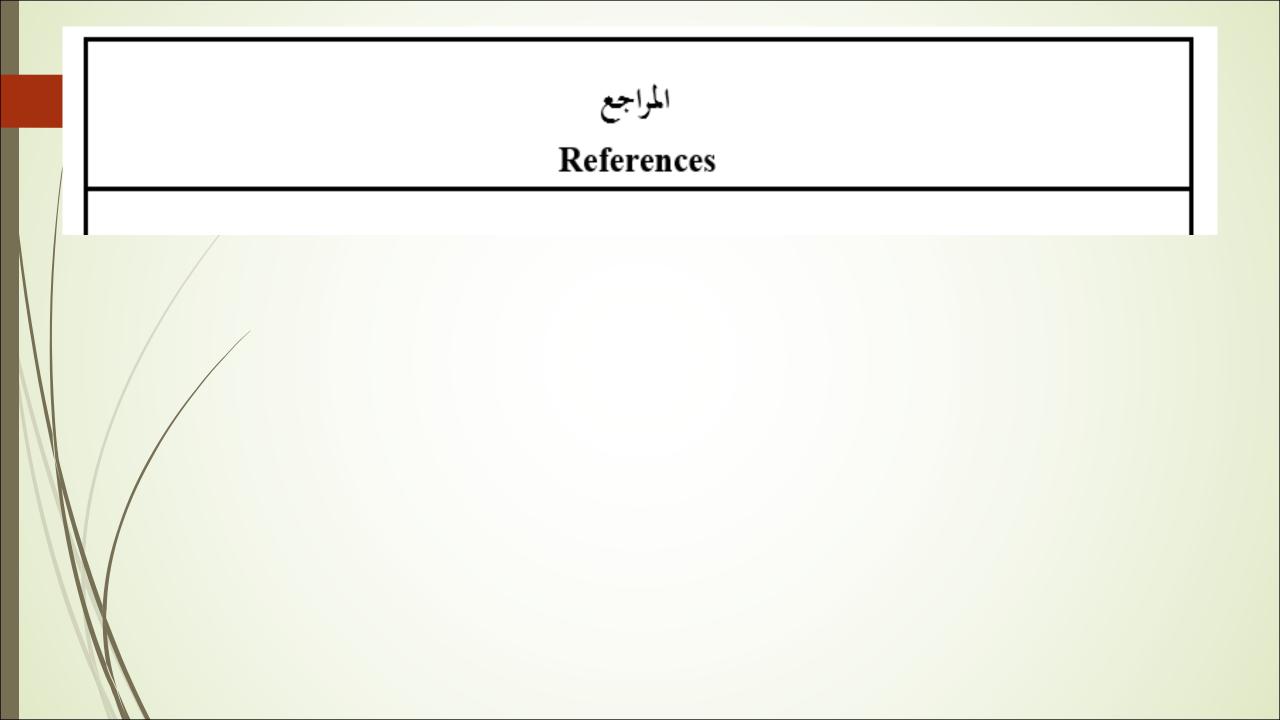
(متغيرات الدراسة) Study Variables:

Ethical Considerations: (الاعتبارات الاخلاقية)

(جمع البيانات / البيانات المصدر) :Data Collection/Data Source

Questionnaires/data Sheets from other authors (Copyrights or permission to use, or open access for academic and research purpose)

(تحليل احصائي) : Statistical Analysis



#### **ROLE OF INVESTIGATORS**



Investigators Names	Brief Description of the Role of Each Investigator		
	Supervising, conceived the topic, study design, data collection, analysis and interpretation of data, writing and drafting.		
	Setting objectives, study design, data collection, analysi and interpretation of data, writing and drafting.		

# Importance of Research Protocol

- Develop novel ideas during writing proposal.
- Convince yourself and others that your research is worth doing.
- Keep you focused on your research work
- A manual for members of the research team to ensure they adhere to the methods outlined

# research problem

A situation for which we have no ready & successful response by instinct or by previous acquired habit
An area of concern where there is a gap in the knowledge base needed for professional practices

#### research problem

- This is where you explain the research problem and question
- This section states the problem that you are exploring.
- It must consist of or address five components:
  - Defining the problem,
  - Showing the severity of the problem,
  - showing the extent of the problem,
  - showing the gap analysis,
  - Finally set the research questions.

#### research problem

- The research question is specific, concise, and clear. The research question can be expanded upon by stating sub-questions.
- Note: The difference between the research problem and research question is that the problem is broader, while the research question represents the "one question that you will answer at the end of your research

### research Significance

- State concisely and clearly the importance of your study.
- Emphasize on any novelty or innovation
- Convey the significance of your research to
  - 1) scientific contribution
  - 2) improving in public health
  - (-3) change in health policies
  - 4) change in patient care



## **Research Objectives**

- This is the place where you have to describe the research aim as it relates to solving the uncertainty or burning question you are interested in.
- It should explicitly hint towards the contribution you want to make with the intended study.
- Need to set both major and specific objectives in a very harnessed way
- Specific objective should not go beyond the major objective even in using action words

## **Research Objectives**

- The research objective should be SMART
- (Specific,
- Measurable,
- Achievable,
- Relevance
- Time bound

## **Literature Review**

- A critical, objective summary of the known extent of the problem and confirms that the research question is appropriate
- Reference should be made to the findings of studies performed internationally and locally to address the problem
- Attention should be drawn to the positives, negatives and limitations of the studies quoted
- The review should include the most recent publications in the field
- Go from general to specific

#### **Literature Review**

- Novel methods and those particularly suited to local circumstances should be highlighted
- Relate key words to dependent and independent variables
- By the end of the review it should be clear that the researcher has a thorough understanding of the problem and why the proposed study design has been chosen, based on gaps in knowledge and conflicting results

#### **Literature Review**

- Logical Flow
  - Keep related ideas together under the same subheading
  - Literature review is a summary of other's findings
  - Methods are those chosen for the thesis
  - Results are new findings of the study
  - Discussion is about the results of the study, new literature should not be included
  - Conclusions are related to research question/ hypothesis/ objectives
  - It should not be a series of unconnected summaries of studies, but rather a synthesis of previous related literature

#### Thank You and Questions

