

# Summary: Introduction to Medical Research Methods

Munir Abu-Helalah MD MPH PhD

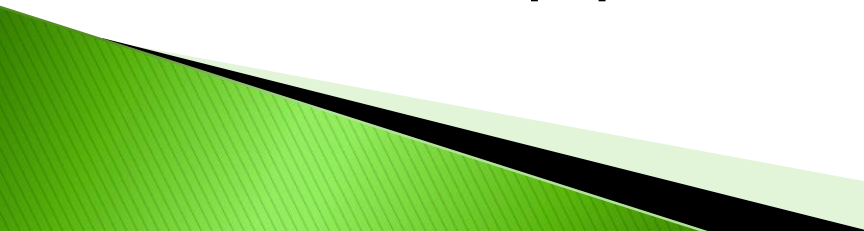
Associate Professor, Consultant of Epidemiology and Preventive Medicine

Department of Family and Community Medicine


School of Medicine

Jordan University

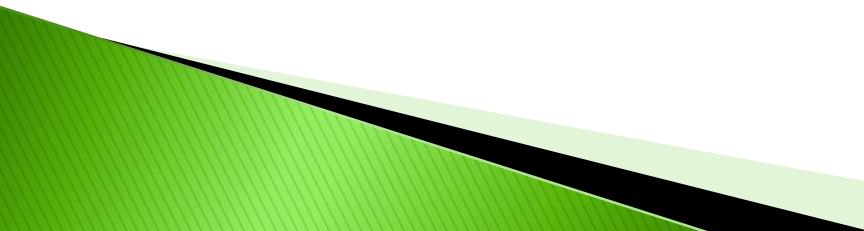
# Key objectives

- ▶ To discuss approaches for transferring ideas into a structured research question
  - ▶ To assist students in development of good research question
  - ▶ To provide students with skills for conducting a comprehensive and structured literature review
  - ▶ To providing good understanding of the duties of the research team
  - ▶ To provide an overview of the research authorship policies
- 


# Research

- ▶ It is a **systematic** investigation to develop or contribute to generalizable knowledge.
  - ▶ Research is an organized and **systematic** way of finding better answers to questions.
- 


# Research

- ▶ Research is vital for the understanding of the problems that affect individuals, communities or health systems.
  - ▶ It allows for **a systematic and scientific assessment or evaluation** of problem and provides knowledge that allows for change to occur– change that improve the quality of health and health care.
  - ▶ No organization or health institution can grow or develop without the use of research.
- 


# Research

- ▶ The basic function of research is to answer why and how of a phenomenon,
  - ▶ but searching answers to
    - what,
    - when,
    - how much, etc., is also part of research endeavours.
- 


# Medical Research

- ▶ The goal of *medical research* is to improve health, and the purpose is to learn how systems in human body work, why we get ill, and how to get back to health and stay fit, and how to prevent illnesses.
  - ▶ It is a **systematic** process to better determine etiology, patho-physiology, epidemiology, diagnosis, therapy, prognosis and prevention.
  - ▶ Research is the very foundation of improved medical care.
  - ▶ It can also provide evidence for policies and decisions on health development.
- 

# Areas of Research


- ▶ Problem(s) discovery, finding
  - ▶ Impact of the problem
  - ▶ Epidemiology of the problem: Size, etiology / risk factors
  - ▶ Pathogenesis
  - ▶ Management
  - ▶ Prevention
- 

# Research Methods

- ▶ Research Methods are the tools and techniques for doing research.
  - ▶ It covers all the steps from planning to carry out research till dissemination of the results.
- 



# STEPS IN MEDICAL RESEARCH

- I. Identify the problem
  - II. Collect and evaluate existing information
  - III. Make your research team
  - IV. Formulate research objectives and hypotheses
  - V. Identify study subjects
  - VI. Think of the design
  - VII. Write the proposal and protocol
  - VIII. Develop the tools
  - IX. Identify Study sites
  - X. Get the necessary permission (Institutional, ethical, etc.)
- 

# Epidemiological studies

Clinical observation

Descriptive studies

Analytical studies

Experimental studies

Variation

Association

Association

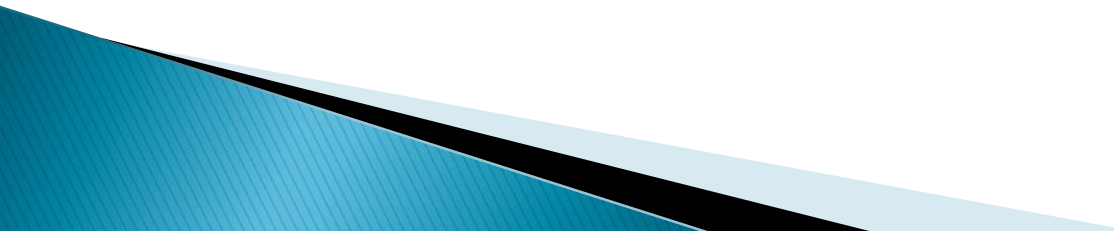
# Moving from research idea to a feasible research project

- ▶ Literature review:

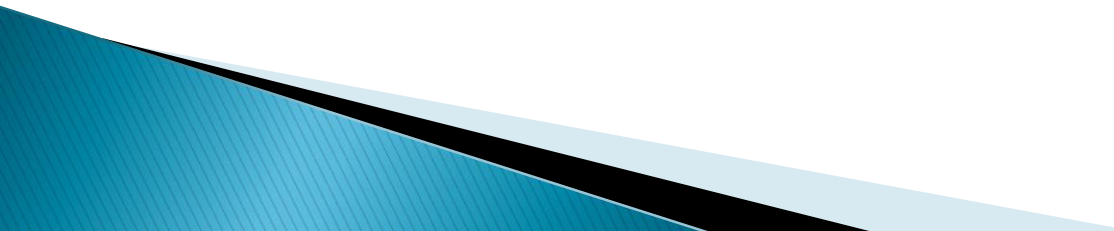
Has it been investigated?

What has been done in this field?

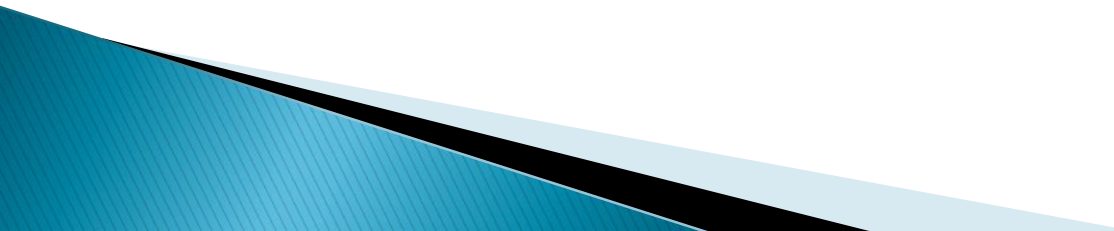
Questions to be answered in this field?



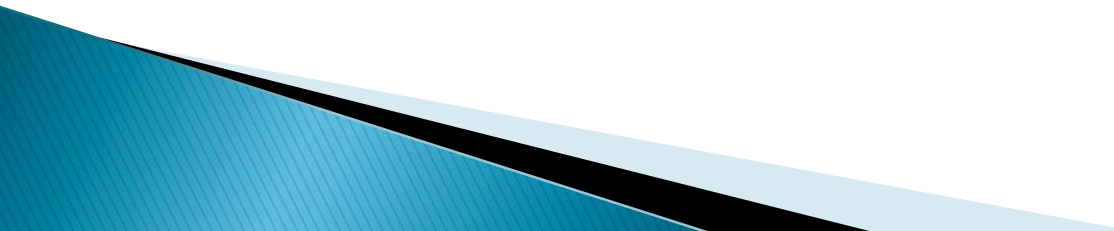
# What is a research question?

- ▶ The researcher asks a very specific question and tests a specific hypothesis.
  - ▶ Broad questions are usually broken into smaller, testable hypotheses or questions.
  - ▶ Often called an objective or aim, though calling it a question tends to help with focusing the hypothesis and thinking about how to find an answer
- 

# ***What characterizes a good question?***

- Well-conceptualized
  - Relevant
  - Direct and clear
  - Focused
  - Includes all components (main concepts)
- 

# How to focus your question?

- ▶ Literature search for previous evidence: focus on reviews, recent updates...etc.
  - ▶ Discuss with colleagues
  - ▶ Attend scientific meetings
  
  - ▶ Narrow down the question – time, place, group
  
  - ▶ What answer do you expect to find?
- 

# Moving from research idea to research question

- ▶ Think about how your research:
  - \* may resolve theoretical questions in your area
  - \* may develop better theoretical models in your area
  - \* may identify new risk factors for a disease
  - \* may change current management plans

# IDENTIFY THE PROBLEM



Convert the problem to specific questions that require answer.



The question must pass the —so what?|| test.




A good research question is backed up by theoretical considerations.



If you are investigating the role of a particular type of diet in urological malignancies, it is helpful to consider why that type of diet can alter the risk of this cancer. Biological plausibility gives a definite edge.



# Clinical example:

- **Too broad:** How do you control infection?
    - This topic is so broad that you'd have difficulty wading through all of the results.
  - **Too narrow:** At the Jordan University Hospital Neonatal Intensive Care Unit, what is the best way to control infections among preterm infants?
    - This question is so specific that there probably hasn't been anything published on that specific location regarding that specific population.
  - **Just right:** In the NICU, JUH, what is the effect of hand washing on infection control compared with hand sanitizers, over 6 months?
- 

## Frameworks for Research Questions

Applying a framework when developing a research question can help to identify the key concepts and determine inclusion and exclusion criteria.

<b>PICo:</b>	Population/Participants, phenomenon of Interest, Context
<b>PICO(S):</b> —	Patient/Problem, Intervention, Comparison, Outcome, (Study design)
<b>PECO(S):</b>	Patient/Problem, Exposure, Comparison, Outcome, (Study design)
<b>PESICO:</b>	Person, Environment, Stakeholders, Intervention, Comparison, Outcome
<b>PIPOH:</b>	Population, Interventions, Professionals/Patients, Outcome, Healthcare Setting
<b>PS:</b>	Population, Situation
<b>SPICE:</b>	Setting, Perspectives, Intervention, Comparison, Evaluation

P (Patient, Population, Problem)	I (Intervention)	C (Comparison)	O (Outcome)
How would I describe a group of patients similar to mine?	What main interventions, prognostic factors or exposure are you considering?	What is the main alternative to compare with the intervention?	What can you hope to accomplish, measure, improve or effect?
In: Otherwise healthy children...	Does: exposure to in utero smoking/nicotine...	Versus: children not exposed to in utero nicotine...	Result in: increased risk of learning disabilities?
In: Primary school children	Does: school-based physical activity	Versus: no school-based physical activity	Result in: a decrease in obesity

# PICOT

- ▶ PICOT is a mnemonic that helps you remember the key components of a well-focused question. It stands for:
  - **P** = Patient, Population or Problem
  - **I** = Intervention, Prognostic Factor, or Exposure
  - **C** = Comparison (optional)
  - **O** = Outcome
- ▶ **T** = Time

## ▶ Intervention/therapy

- ▶ In \_\_\_\_\_(P), what is the effect of \_\_\_\_\_(I) on \_\_\_\_\_(O) compared with \_\_\_\_\_(C) within \_\_\_\_\_(T)?
- ▶ In the aged population, what is the effect of exercise programs on accidental falls, as compared with no exercise?


## ▶ Etiology

- ▶ Are \_\_\_\_\_(P) who have \_\_\_\_\_(I) at \_\_\_\_\_(Increased/decreased) risk for/of \_\_\_\_\_(O) compared with \_\_\_\_\_(P) with/without \_\_\_\_\_(C) over \_\_\_\_\_(T)?
- ▶ Are adult smokers with a history of childhood asthma at increased risk of COPD compared to adult smokers with no history of asthma?

## ▶ **Diagnosis or diagnostic test**

- ▶ Are (is) \_\_\_\_\_ (I) more accurate in diagnosing \_\_\_\_\_ (P) compared with \_\_\_\_\_ (C) for \_\_\_\_\_ (O)?
- ▶ Is the combination of fasting glucose with Hemoglobin A1C test more valid for screening for type II diabetes as compared with fasting blood sugar levels?

## **Prevention**

- ▶ For \_\_\_\_\_ (P) does the use of \_\_\_\_\_ (I) reduce the future risk of \_\_\_\_\_ (O) compared with \_\_\_\_\_ (C)?
  - ▶ For people with type 2 diabetes, does zinc supplementation reduce the future risk of foot ulcers compared with placebo?
- 

▶ **Prognosis/Predictions**

- ▶ Does \_\_\_\_\_ (I) influence \_\_\_\_\_ (O) in patients who have \_\_\_\_\_ (P) over \_\_\_\_\_ (T)?
- ▶ In adults with osteoarthritis, does low vitamin D levels in the bloodstream predict the rate of future hip fractures?

▶ **Meaning**

- ▶ How do \_\_\_\_\_ (P) diagnosed with \_\_\_\_\_ (I) perceive \_\_\_\_\_ (O) during \_\_\_\_\_ (T)?
- ▶ How do cancer patients diagnosed with alopecia perceive their self-esteem during and after chemotherapy?

# Public Health:

▶ PICO(T) is commonly used to formulate research questions, sometimes referred to as 'PI/ECO' (Population/participants, Intervention/Exposure, Comparison, Outcome). The PI/ECO structure can be readily amended for different question types:

▶ A simple example might be:

- **Population / participants:** People with permanent residence in Jordan
- **Intervention (or Exposure):** Hypertension
- **Comparison:** Respondents without hypertension
- **Outcomes:** Cardiovascular disease or cardiovascular mortality
- **Types of studies:** Cross-sectional, Longitudinal



# Public Health:

## Formulating Research Questions

**Underdeveloped question:** ▶


What interventions help against smoking vaping in youth? •

**Refined research question:** ▶

What strategies help prevent e-cigarette use in adolescents? •


# Literature review

Literature review is required through your research:

- ▶ It helps to choose topic
  - ▶ Prevents from duplicating work
  - ▶ Refine your problem
  - ▶ Formulate objectives
  - ▶ Familiar with various methodology
  - ▶ Provide argument why is it needed (justification)
- 

# Literature review

Writing a literature review lets you gain and demonstrate skills in two areas

- ▶ **information seeking:** the ability to scan the literature efficiently, using manual or computerized methods, to identify a set of useful articles and books
  - ▶ **critical appraisal:** the ability to apply principles of analysis to identify unbiased and valid studies.
- 

# Literature Review


## b. Improve your methodology:

- ▶ A literature review tells you:
  - I. If others have used procedures and methods similar to the ones that you are proposing?
  - II. Which procedures and methods have worked well for them?
  - III. What problems they have faced with them?
- ▶ **Thus you will be better positioned to select a methodology that is capable of providing valid answer to your research questions.**


# Literature Review

Broaden your knowledge base in your research area:

It ensures you to read widely around the subject area in which you intend to conduct your research study.


- ▶ As you are expected to be an expert in your area of study, it helps fulfill this expectation.
  - ▶ It also helps you to understand how the findings of your study fit into the existing body of knowledge.
- 

# Literature Review

1. books
  2. Journals
  3. Medical databases: PubMed, Medline..etc.
  4. Other publications:  
(reports, census, surveys etc)
  5. Other Internet search  
(**scientific evidence based sites or sites of official medical bodies**)
- 

# Literature Review

## BOOKS

- ▶ comprise a central part of any bibliography.
  - ▶ Advantage—material published generally is of good quality and the findings are integrated with other research to form a coherent body of knowledge.
  - ▶ Disadvantage—material is not completely up to date, as it can take a few years between the completion of a work and publication in the form of a book.
- 

# Literature Review

## JOURNALS

- ▶ Journals provide you with the most up-to-date information
- ▶ **Be careful with open access journals without solid peer review process**



# Resources

- ▶ Pubmed
- ▶ Popline
- ▶ CDC
- ▶ Google scholar
- ▶ UN
  - WHO
    - emro
  - UNICEF
    - UNICEF Jordan
  - UNDP
  - UNEP
  - UNFPA/ UNAIDS/ UN women
- ▶ DHS
- ▶ NICE,UK


# How to start and end the literature review/introduction part

## ▶ Starting with:


- a. Common illness: burden, epidemiology and complications, current clinical guidelines and recommendations
- b. Rare or uncommon condition: definition

## End with:


Key limitation or areas of need, your question, aim of your study, 2 lines on your study design and your study population.



## From a research question to a proposal

- ▶ who am I collecting information from?
  - ▶ what kinds of information do I need?
  - ▶ how much information will I need? how will I use the information?
  - ▶ How to reach the whole population or a representative sample
  - ▶ how will I minimise chance/bias/confounding?
  - ▶ how will I collect the information ethically?
- 

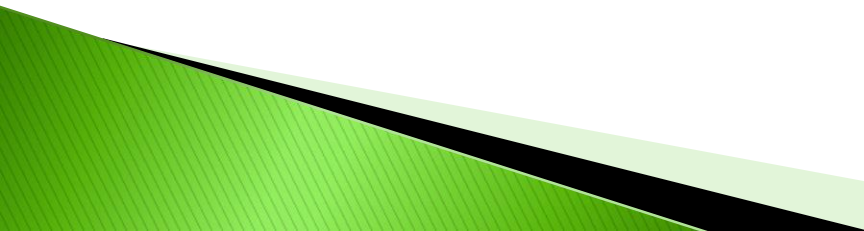
# Key components of research proposal:

- A description of the research problem.
  - An argument as to why that problem is important.
  - A review of literature relevant to the research problem.
  - A description of the proposed research methodology.
  - A description of how the research findings will be used and/or disseminated.
- 

# Key steps in conducting medical research


- Answers relevant questions
  - ✓ Public health problem: Important?
  - ✓ Study question: relevant to the problem?
  - ✓ Objectives: consistent with the study question?
  - ✓ Study design: achieves objectives?
  - ✓ Your sample is representative?
  - ✓ Power of the study: sufficient?
  - ✓ Public health impact of the findings?

# Plagiarism

- ▶ Plagiarism is using others' ideas and words without clearly acknowledging the source of that information.
  - ▶ To avoid plagiarism, you must give credit whenever you use
    - another person's idea, opinion, or theory;
    - any facts, statistics, graphs, drawings—any pieces of information—that are not common knowledge;
    - quotations of another person's actual spoken or written words; or
    - paraphrase of another person's spoken or written words.
- 

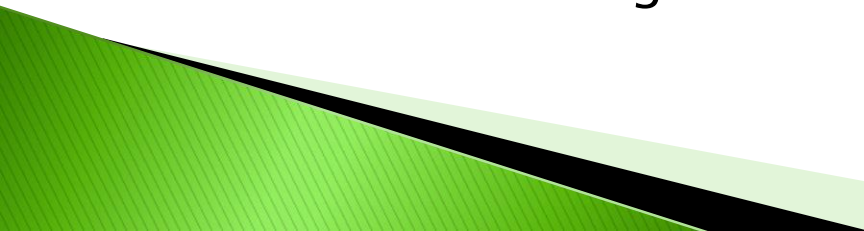
# Plagiarism

## ► Strategies for Avoiding Plagiarism

1. Put in **quotations** everything that comes directly from the text especially when taking notes.
  2. **Paraphrase**, but be sure you are not just rearranging or replacing a few words.
  3. **Check your paraphrase** against the original text to be sure you have not accidentally used the same phrases or words, and that the information is accurate.
- 

# Plagiarism

## Terms You Need to Know

- ▶ **Common knowledge:** facts that can be found in numerous places and are likely to be known by a lot of people.
    - You do not need to document this fact.
    - However, you must document facts that are not generally known and ideas that interpret facts.
  - ▶ **Quotation:** using someone's words. When you quote, place the passage you are using in quotation marks, and document the source according to a standard documentation style.
  - ▶ **Paraphrase:** using someone's ideas, but putting them in your own words.
    - Although you use your own words to paraphrase, you must still acknowledge the source of the information.
- 



# Set Research Objectives

The **research objective** is a statement which **clearly describes what the researcher(s) aims to achieve from a research.**

It should be **broken down between (1) a general objective and (2) specific objectives.**

Remember:

A good research needs to be both relevant AND methodologically sound!



## **Components Of Research Objectives**

Effective research objectives consist of specific, measurable, achievable, relevant, and time-bound (SMART) components, providing clarity and guiding the research study toward desired outcomes and focused investigation.





**S**

**Specific**

State what you'll do  
Use action words



**M**

**Measurable**

Provide a way to  
evaluate  
Use metrics or data  
targets



**A**

**Achievable**

Within your scope  
Possible to accom-  
plish, attainable



**R**

**Relevant**

Makes sense within  
your job function  
Improves the  
business in some  
way



**T**


**Time-bound**

State when you'll get  
it done  
Be specific on date  
or timeframe


# National Study on RSV epidemiological, clinical and financial burden in Jordan among children younger than 5 years of age

**Aim:** The aim of this study is to provide an assessment of the epidemiology, health and economic burden of Respiratory syncytial virus (RSV) infections in Jordan amongst hospitalized children under 5 years of age.

## **Objectives:**

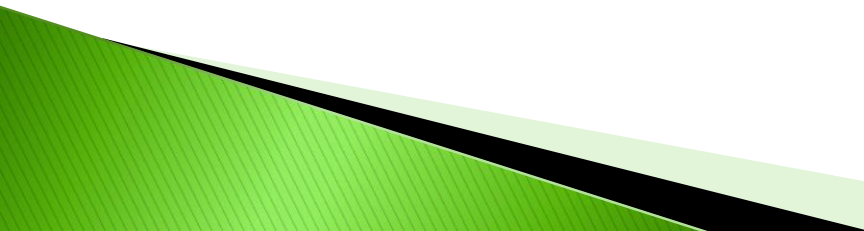
1. To examine the epidemiology of RSV infections in children under than 5 years of age.
  2. To assess the proportion of RSV virus epidemiology compared with other common respiratory infections based on the PCR results.
  3. To assess the severity of RSV infections amongst hospitalized patients in Jordan.
  4. To assess the risk factors for RSV infection.
  5. To quantify the direct and indirect medical along with societal costs of RSV infections amongst hospitalized patients in Jordan.
- 

# Research team

- ▶ Team Members
  - ▶ A group of individuals working toward a common goal: that's what a research team is all about.
  - ▶ In this case, the shared goal between team members is the successful research, data analysis, publication and dissemination of meaningful findings.
  - ▶ There are key roles that must be laid out BEFORE the project is started, and the "Project Lead", namely the Principal Investigator must provide all the resources and training necessary for the team to successfully complete its mission.
- 

# Principal Investigator (PI):

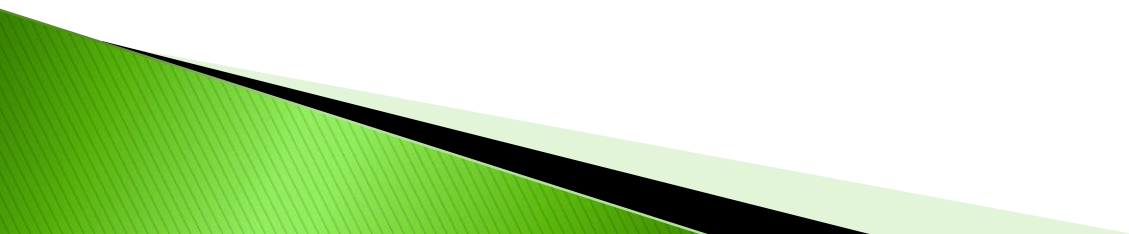
1. this is the person ultimately responsible for the research and overall project.

- ▶ He needs to ensure that the team members have the information, resources and training they need to conduct the research.
  - ▶ He is also the final decision maker on any issues related to the project.
  - ▶ Some projects have more than one PI, so the designated individuals are known as Co-Principal Investigators.
  - ▶ PIs are also typically responsible for writing proposals and grant requests, and selecting the team members.
  - ▶ They report to their employer, the funding organization, and other key stakeholders, including all legal as well as academic regulations.
  - ▶ The final product of the research is the article, and the PI oversees the writing and publishing of articles to disseminate findings.
- 

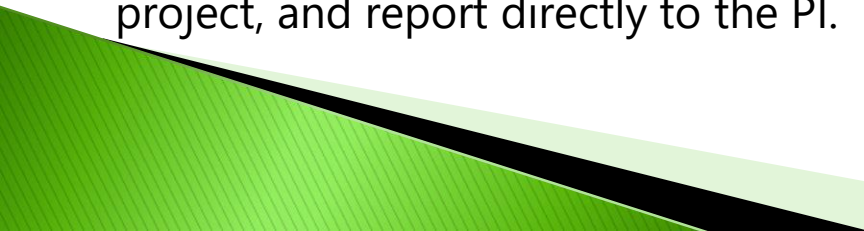
# **Sub-Investigator (Sub-I) / Co-Investigator (Co-I)**

The Sub-Investigator/Co-Investigator may perform all or some of the PI functions, but they do not accept primary responsibility for the research study.

The sub-investigator/co-Investigator is under the supervision of the PI and is responsible for performing study-related procedures and /or to make important study-related decisions in compliance with the ethical conduct of the study.




# Project or Research Director/manager


- ▶ This is the individual who is in charge of the day-to-day functions of the research project, including protocol for how research and data collection activities are completed.
  - ▶ Mainly appointed in large observational studies and in clinical trials
  - ▶ The Research Director/Manager directs directly to the PI and works very closely with him/her.
  - ▶ Specifically, this individual assist the PI in the supervision of the project, direct any protocol as needed, acts as the manager of the team in regards to time, duties and budget, and evaluates the progress of the project.
  - ▶ The Research Director/manager also makes sure that the project is in compliance with all guidelines, including governmental and institutional review board regulations.
  - ▶ They also usually assist the PI in writing the research articles related to the project, and report directly to the PI.
- 



# 3. Research Assistant:


- ▶ This individual, or individuals, perform the day-to-day tasks of the project, including collecting data, maintaining equipment, follow up samples collection and analysis, etc.
  - ▶ Typically, the research assistant has the least amount of experience among the team members.
  - ▶ Research Assistants usually report to the Research Associate/Project Coordinator, and sometimes the Statistician.
- 

# 4. Biostatistician:


- ▶ This is the individual who analyzes any data collected during the project.
  - ▶ Sometimes they just analyze and report the data, and other times they are more involved in the organization and analysis of the research throughout the entire study.
  - ▶ Their primary role is to make sure that the project produces reliable and valid data, and significant data via analysis methodology, sample size, etc.
  - ▶ The Statistician reports both to the Principal Investigator and the Research Director.
  - ▶ Research teams may include people with different roles, such as clinical research specialists, interns, student researchers, lab technicians, grant administrators, and general administrative support staff.
- 

# Defining the Role of Authors and Contributors

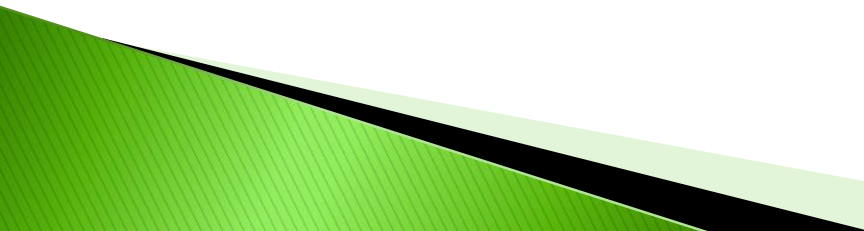
## *1. Why Authorship Matters*

- ▶ Authorship confers credit and has important academic, social, and financial implications.
  - ▶ Authorship also implies responsibility and accountability for published work.
  - ▶ It is always recommended to make a clear plan in the study protocol on the authorship order with conditions for changing this order
  - ▶ Because authorship does not communicate what contributions qualified an individual to be an author, some journals now request and publish information about the contributions of each person named as having participated in a submitted study, at least for original research.
- 


# *1. Why Authorship Matters*

- ▶ Editors are strongly encouraged to develop and implement a contributorship policy.
  - ▶ Such policies remove much of the ambiguity surrounding contributions, but leave unresolved the question of the quantity and quality of contribution that qualify an individual for authorship.
- 


## *2. Who Is an Author?*

- ▶ Authorship be based on the following 4 criteria:
    1. Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
    2. Drafting the work or reviewing it critically for important intellectual content; AND
    3. Final approval of the version to be published; AND
    4. Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.
  - ▶ In addition to being accountable for the parts of the work done, an author should be able to identify which co-authors are responsible for specific other parts of the work.
  - ▶ In addition, authors should have confidence in the integrity of the contributions of their co-authors.
- 


## *2. Who Is an Author?*

- ▶ All those designated as authors should meet all four criteria for authorship, and all who meet the four criteria should be identified as authors.
  - ▶ Those who do not meet all four criteria should be acknowledged.
  - ▶ These authorship criteria are intended to reserve the status of authorship for those who deserve credit and can take responsibility for the work.
  - ▶ Therefore, all individuals who meet the first criterion should have the opportunity to participate in the review, drafting, and final approval of the manuscript.
- 

# Coauthors


- ▶ The individuals who conduct the work are responsible for identifying who meets these criteria and ideally should do so when planning the work, making modifications as appropriate as the work progresses.
  - ▶ We encourage collaboration and co-authorship with colleagues in the locations where the research is conducted.
  - ▶ It is the collective responsibility of the authors, not the journal to which the work is submitted, to determine that all people named as authors meet all four criteria.
- 

# Coauthors


- ▶ If agreement cannot be reached about who qualifies for authorship, the institution(s) where the work was performed should be asked to investigate.
  - ▶ The criteria used to determine the order in which authors are listed on the byline may vary, and are to be decided collectively by the author group and not by editors.
  - ▶ If authors request removal or addition of an author after manuscript submission or publication, journal editors should seek an explanation and signed statement of agreement for the requested change from all listed authors and from the author to be removed or added.
- 



# The corresponding author

- ▶ The corresponding author is the one individual who takes primary responsibility for communication with the journal during the manuscript submission, peer-review, and publication process.
  - ▶ The corresponding author typically ensures that all the journal's administrative requirements, such as providing details of authorship, ethics committee approval, clinical trial registration documentation, and disclosures of relationships and activities are properly completed and reported, although these duties may be delegated to one or more co-authors.
- 

# The corresponding author

- ▶ The corresponding author should be available throughout the submission and peer-review process to respond to editorial queries in a timely way, and should be available after publication to respond to critiques of the work and cooperate with any requests from the journal for data or additional information should questions about the paper arise after publication.
  - ▶ Although the corresponding author has primary responsibility for correspondence with journals
- 

# *3. Non-Author Contributors*

- ▶ Contributors who meet fewer than all 4 of the above criteria for authorship should not be listed as authors, but they should be acknowledged.
  - ▶ Examples of activities that alone (without other contributions) do not qualify a contributor for authorship are acquisition of funding; general supervision of a research group or general administrative support; and writing assistance, technical editing, language editing, and proofreading.
- 