



## Objectives:

1. Appreciate the importance of ethics in research
2. Understand the principles of research ethics
3. Appreciate the ethical requirement of research

# Ethics in health research



## Our Team:



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## Editing file



Black: in male AND female slides  
Red : important  
Gray: extra information

# Research

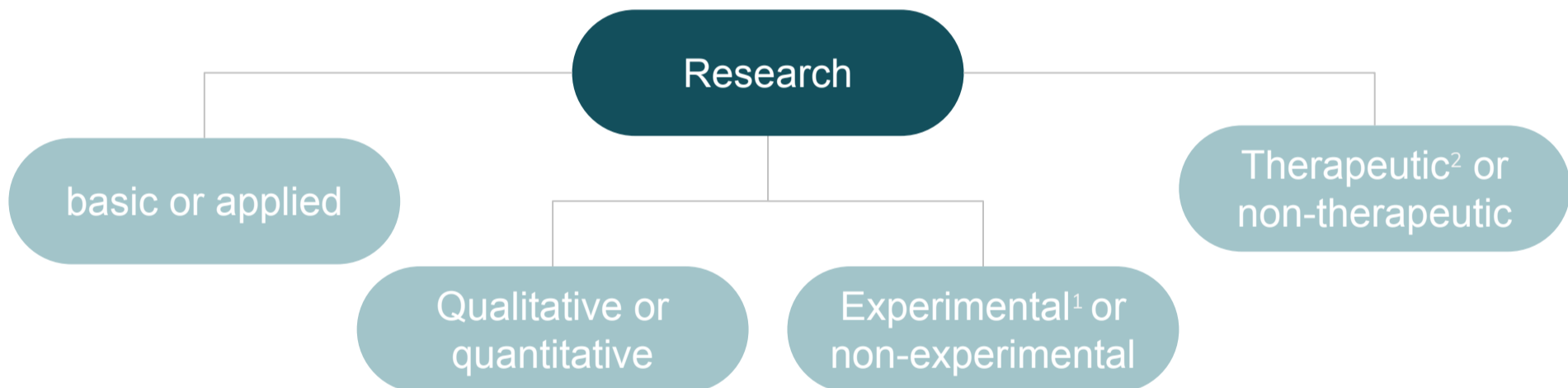
## What is research ?

- Research is a careful study of a given subject , a process of discovering new knowledge.  
Originally Halal but it depends on the objectives+methods

## Research and medical practice

- Research :
  - ◆ A class of activities designed to develop or contribute to generalizable knowledge
  - ◆ A careful and detailed study into a specific problem, concern, or issue using the scientific method
- Practice : A class of activities designed solely to enhance the wellbeing of individual patient.  
Diagnosis, preventive treatment or therapy.

## Classes of research



## Phases Of clinical research

| Preclinical                 | Clinical   |  |   |                 |                            |
|-----------------------------|--|--|---|-----------------|----------------------------|
| Animal / Laboratory studies | Phase 1<br>15-30 volunteers  | Phase 2<br><100 volunteers                             | Phase 3<br>100 - 1000s volunteers   | FDA Approval    | Phase 5 (after approval)   |
| About 4.5 years             | Tolerability<br>Pharmacokinetics<br>Pharmacodynamics<br>Aim to see | Effectiveness<br>Dosage safety<br>Proper medical trial | Comparison<br>Effectiveness<br>Side effects<br>Phase 1+2+3 =<br>About 8.5 years | About 1.5 years | Comparison<br>Side effects |

1: We intervene → we must have great explanation for intervention

2: More concerning ethically: pt won't benefit at all

We start first (0) المرحلة working in the animals in the lab بعدها اذا شغنا انه كان امن ننتقل للمرحلة الاخير ونطلب متطوعون من ١٥-٣٠ we look or the pharmacokinetics-pharmacodynamics المرحلة الثالثة  
 تاخذ عدد اكبر من المتطوعين ما يكون اقل من ١٠٠ وغالبا مو مرضى نحدد فيها Effectiveness, dosage , safety ..  
 المرحلة ٣ اللي بعدها نزيد عدد المتطوعين الى 100-1000 هنا بتبدأ عملية المقارنة محدد اول ال side effects , effect of drug مثل اللي يصير الحين بكوفيد فاكسين اغلب الناس خايفه من الضرر على المد البعيد لكن القصير عرفناه بعد التجربة على طول اخر مرحلة 4 ال after approval يُطلق الدواء ( بعد ماتم تجربته لفترة طويلة )

# Research & Ethics

## Nuremberg Code

- INFORMED CONSENT
- QUALIFIED RESEARCHER
- APPROPRIATE RESEARCH DESIGN
- FAVORABLE RISK/BENEFIT RATIO
- PARTICIPANT FREEDOM TO STOP

## Purpose of Islamic Sharea

- PROTECTION OF RELIGION
- PROTECTION OF HUMAN LIFE
- PROTECTION OF THE MIND
- PROTECTION OF PROGENY
- PROTECTION OF PROPERTY

## Is Research obligatory?

- IF AN OBLIGATION CANNOT BE COMPLETED EXCEPT WITH SOMETHING, THAT (SOMETHING) BECOME OBLIGATORY.
- ما لا يتم الواجب الا به فهو واجب فرض كفايه

## The care principle

- "You all a shepherd who is responsible for all of his heard"
- كلکم راع وکلکم مسؤول عن رعیتہ

# Research & Ethics

## Importance of ethics in research

- Protection of participants
- Safeguard against exploitation
- Ensure respect of individuals , dignity , confidentiality & privacy
- Ensure good clinical practice in research
- Safeguard against violations in research & research misconduct.

## General islamic principles related to research ethics

- Devotional purposes & purposes of law.
- Best interest.
- Preventing & elimination harm.
- Consequences.
- Protecting rights.
- Duty of care & caring.
- Observing moral principles & virtues.
- Good treatment / dealing with people.
- Observing fiqh principles.

- تحقيق الجانب الإيماني و القصد التعبدي.
- تحقيق و حفظ المقاصد الشرعية الإسلامية.
- تحقيق المصلحة.
- دفع الضرر و رفعه.
- تقدير المآلات.
- حفظ الحقوق.
- تحقيق واجب الرعاية.
- قواعد أخلاقية يجب مراعاتها.
- حسن الخلق في التعامل مع الناس.
- مراعاة القواعد الفقهية.

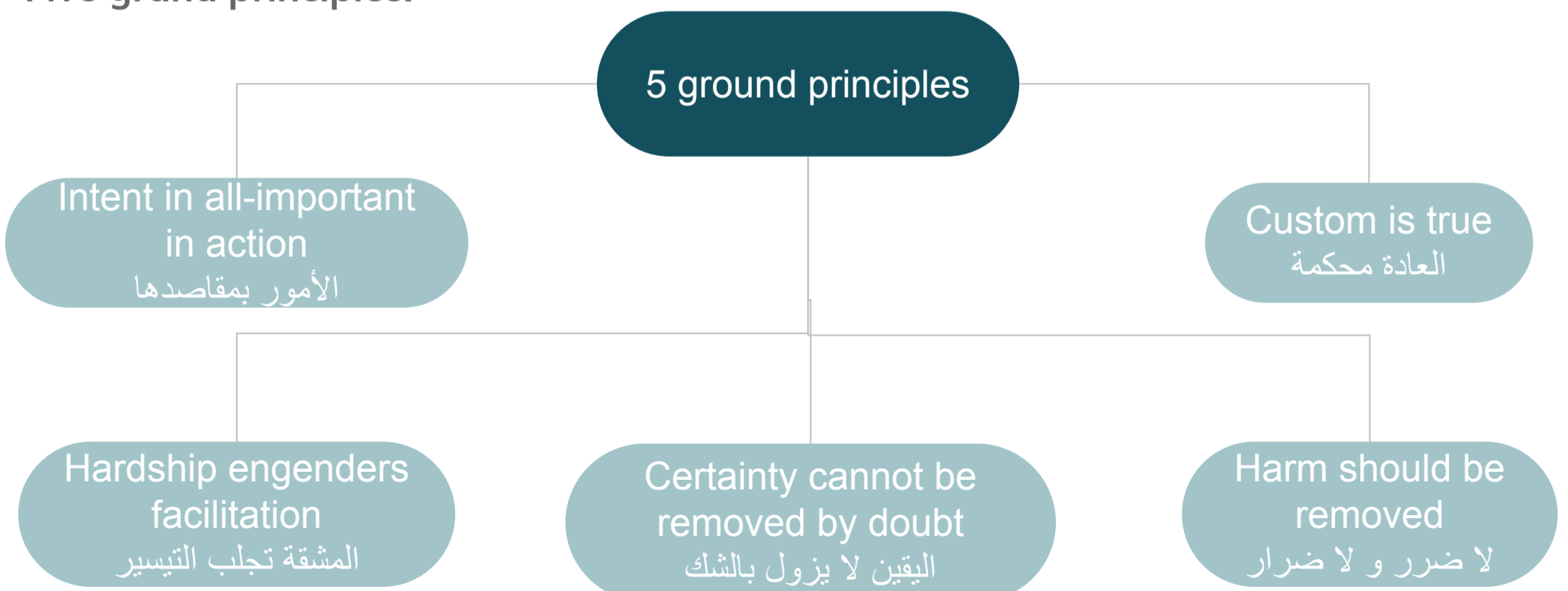
## Major principles of research in islam

Two major principles:

**The accrument of benefits**

**The warding off of harm**

Five grand principles:

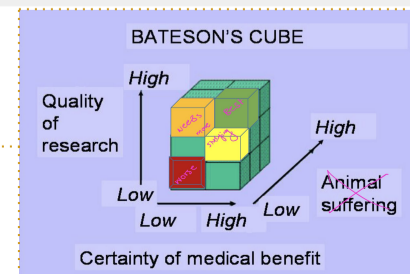


# Ethical Requirements

|  |   |
|--|---|
| <p>Scientific Value</p>                              | <ul style="list-style-type: none"> <li>- Responsible use of finite resources vs No value or trivial value</li> <li>- Avoidance of exploitation</li> <li>- Not to expose human being to potential harms without some possible social or scientific benefit</li> <li>- Prioritization</li> </ul>  |
| <p>Independent Review</p>                            | <ul style="list-style-type: none"> <li>- Proposed subject population</li> <li>- Review design</li> <li>- Risk Benefit Ratio</li> </ul> <p style="text-align: center;">“ Conflict of interest “</p>  |
| <p>Scientific validity</p>                           | <p>Use accepted scientific principles &amp; methods to produce reliable &amp; valid data<br/> <i>Good value but inappropriate method</i></p>  |
| <p>Fair subject selection</p>                        | <p>Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research</p> <p style="text-align: center;">“ JUSTICE “ <i>Do Research in poor countries</i></p>   |
| <p>Respect of Potential &amp; enrolled subjects.</p> | <ul style="list-style-type: none"> <li>- Protecting privacy</li> <li>- New risks or benefits</li> <li>- Result of clinical research</li> <li>- Maintaining welfare of subjects</li> </ul> <p style="text-align: center;">“ Autonomy &amp; right “</p>   |
| <p><b>Favourable risk-benefit ratio</b></p>          | <ul style="list-style-type: none"> <li>- Minimizing Risk</li> <li>- Enhancement of Potential benefits</li> </ul> <p><i>Know the risks and any possible potential damage before starting/approving the research</i></p> <p style="text-align: center;">“ Non- Maleficence , Beneficence “</p>  |
| <p>informed consent</p>                              | <p>It is consent given by a competent individual who:</p> <ol style="list-style-type: none"> <li>1. <b>received</b> the necessary <b>information</b></li> <li>2. has <b>adequately understood the information</b></li> <li>3. after considering the information, has <b>arrived at a decision</b> without been subject to coercion, undue influence or inducement or intimidation.</li> </ol> |

Observance of sharia principles and law  
Observance of the local laws/policies

Bateson's cube evaluates proposed research through three criteria: the degree of animal suffering, the quality of the research, the potential medical benefit.



# Informed Consent

## Definition

Is a process by which an individual voluntarily expresses his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the decision to participate

## Conditions



## Essential elements

- ◉ A statement that the study involves research
- ◉ A description of any reasonably foreseeable risks or discomforts to the subject.
- ◉ A description of any expected benefits to the subject or to others.
- ◉ A disclosure of appropriate alternative procedures or courses of treatment, if any
- ◉ Assurance of confidentiality
- ◉ A statement about compensation
- ◉ Contact details
- ◉ Assurance of voluntariness of participation

## Additional elements (not imp,skip)

- ◉ Unforeseeable risks
- ◉ Termination of participation
- ◉ Additional costs

- ◉ Consequences of withdrawal
- ◉ Significant new findings
- ◉ Number of participants

# Informed Consent Cont.

## Informed consent readability

- **Language:**  
Language of participants , explanation / interpretation , simple language
- **Legibility**
- **Avoid medical jargon**

## Waiver of informed consent

- **Minimal risk**
- **Rights and welfare of participants protected**
- **Research not possible without a waiver**
- **Appropriate information provided**

# Research Virtues & Groups

## Research virtues

- **Sincerity / faithfulness**
- **Observance of Allah**
- **Integrity / honesty : صادق وأمين وهو يراجع**
  - Originality of the study
  - Review of previous studies
  - Truthfulness about the benefits & risks
  - Scientific integrity unethical & capacity able to do the research
  - Impartiality
  - Appropriate research team
  - Observing rights of collaborators people participating in the research

## Research on special (vulnerable Needs more help) groups

- **Definition :**  
A vulnerable participant is an individual who lacks the ability to fully consent to participate in a study  
**Old, women, prisoners, sick, poor**

- **Types of vulnerability -skip-**
  - physical
  - Social
  - Cognitive / communicative
  - Economic
  - Institutional

# Lecture Summary

## Ethics in health Research

|                               |  |                             |                                  |                                |
|-------------------------------|--|-----------------------------|----------------------------------|--------------------------------|
| <b>Definition of Research</b> | <ul style="list-style-type: none"> <li>◆ A class of activities designed to develop or contribute to generalizable knowledge</li> <li>◆ A careful and detailed study into a specific problem, concern, or issue using the scientific method</li> </ul>  |                             |                                  |                                |
| <b>Classes of Research</b>    | Basic or Applied   | Qualitative or Quantitative | Experimental or non-experimental | Therapeutic or non-therapeutic |
| <b>Importance of Ethics</b>   | <ul style="list-style-type: none"> <li>→ Protection of participants</li> <li>→ Safeguard against exploitation</li> <li>→ Ensure respect of individuals , dignity , confidentiality &amp; privacy</li> <li>→ Ensure good clinical practice in research</li> <li>→ Safeguard against violations in research &amp; research misconduct</li> </ul> |                             |                                  |                                |

## General islamic principles related to research ethics

- |   |   |
|---|---|
| <ul style="list-style-type: none"> <li>-Devotional purposes &amp; purposes of law</li> <li>-Best interest</li> <li>-Preventing &amp; elimination harm</li> <li>-Consequences</li> <li>-Protecting rights</li> </ul> | <ul style="list-style-type: none"> <li>-Duty of care &amp; caring</li> <li>- Observing moral principles &amp; virtues</li> <li>- Good treatment / dealing with people</li> <li>-Observing fighi principles</li> </ul> |
|---|---|

## Ethical Requirements

|                  |                    |                     |                        |  |                               |                  |
|------------------|--------------------|---------------------|------------------------|--|-------------------------------|------------------|
| Scientific Value | Independent Review | Scientific validity | Fair subject selection | Respect of Potential & enrolled subjects | Favourable risk-benefit ratio | Informed Consent |
|------------------|--------------------|---------------------|------------------------|--|-------------------------------|------------------|

## Informed Consent

|                   |  |
|-------------------|--|
| <b>Definition</b> | a process by which an individual voluntarily expresses his or her willingness to participate in a particular study, after having been informed of all aspects of the study that are relevant to the decision to participate. |
| <b>Conditions</b> | Right - Cognizance - Capacity- Voluntariness - Lawful Procedure  |



# Questions

**(1) which of the following is one of the importance of ethics?**

- A) Protection of participants
- B) ensure dignity
- C) discovering new drugs
- D) A & B

**(2) Animal and laboratory studies takes about?**

- A) 1.5 years
- B) 2.5 years
- C) 3.5 years
- D) 4.5 years

**(3) which of the following is a major islamic principle in research ?**

- A) warding off of harm
- B) custom is true
- C) intent in all-important in action
- D) hardship engenders facilitation

**(4) which of the following is an ethical requirement?**

- A) scientific validity
- B) Scientific Value
- C) Favourable risk-benefit ratio
- D) all of the above

**(5)an individual who gives informed consent should?**

- A) receive the necessary information
- B) adequately understood the information
- C) Be competent
- D) All of the above

Answers:

1: D, 2: D, 3:A , 4: D 5: D

# Lecture notes 439 ...

الاخلاق لا تقل اهمية عن الانجازات العلمية بذاتها.

البحث يبدأ بسلسلة من الاجراءات التي قد تجيب عن هذا السؤال او قد لا تجيب وتولد سؤال اخر ولكن غالبا تنتهي بالنشر والاخلاق يتعلق بالقضية البحثية من بدايتها الى نهايتها

## Research:

تعني اننا نطمح بمجموعة من الانشطة نطبقها لنجيب على سؤال generalized knowledge

## Practice (important for us as doctors)

كل حالة practice الفرق بينه وبين الرسيرتش هو انه في الرسيرتش بتكون اجابة سؤال قابلة للتطبيق على الكل ولكن في ال تختلف عن اخرى فصعب يتعمم

## Clinical research part of experimental research divided into :

**Therapeutic:** clinical trail where the people who's doing the research on them will benefit therapeutically or not

**Non therapeutic:** patient won't benefit

## Phase of clinical research:

We start first (0)مرحلة working in the animals in the lab بعدها اذا شفنا انه كان امن ننتقل للمرحلة الاخير

المرحلة الثالثة تاخذ عددِ we look or the pharmacokinetics-pharmacodynamics ونطلب متطوعون من ١٥-٣٠

اكبر من المتطوعين مايكون اقل من ١٠٠ و غالبا مو مرضى نحدد فيبيها

Effectiveness, dosage , safety ..

effect of drug , side المرحلة ٣ اللي بعدها نزيد عدد المتطوعين الى 100-1000 هنا بتبدا عملية المقارنة محدد اول ال

مثل اللي يصير الحين بكوفيد فاكسين اغلب الناس خايفه من الضرر على المد البعيد لكن القصير عرفناه بعد التجربة effects

يُطلق الدواء ( بعد ماتم تجربته لفترة طويلة ) after approval على طول اخر مرحلة 4 ال

# Lecture notes 439 ...

## Research ethics:

ليش مهمة؟ (حفظ حقوق فكرية ، المريض الخ...)

1-protection of participants (لانه فيه باحثين يستغلون حاجة الناس)

في الأونة الاخيرة زاد الأهتمام بالاخلاق في البحث بسبب الوقائع المروعة والاجرام اللي صارت

١-تجارب النازية في الحرب العالمية

٢..- الطبيب النازي الذي كان يحدد من من الاسرى قوي ليعيش والاخر ضعيف ليقتل كما انه قام بتجارب كثيرة الخ

هدفه وضع قواعد واضحة لا يتجاوزها احد والمحافظة عليها : Nuremberg code كل هذا اذا الى اطلاق او اصدار او انشاء

! واستمرت ل ٤٠ سنة بدون محد يكتشفهم Tuskegee syphilis study لكن للأسف ما حل المشكلة فبعده حدثت ال

في جنوب افريقيا كانت الدراسة على السود اللي عندهم سفلز (وقيل انه حتى انهم جربوه على اللي ما عندهم )

The idea of the research is history of syphils and the treatment

هدف البحث كان نبيل ولكن طريقتهم المستخدمة لا فهم ما قالو للسود الاليه ولا انه يتم علاجكم وانكم ضمن بحث واستمرو

يراقبونهم بدون ما يدرون في اماكن عامة كماكن مخصصة كمنظمة صحية وياخذون منهم دم على انه دم فاسد

من اهمها Nuremberg code في عام ١٩٧٨ اصدرو تحديث اضافة على (مما فهمت)

يعني يتم اختيار الناس على بناء علمي وليس الضعفاء: Justices (subject selection)

### - is it obligatory?

so we have to do it الى من خلال البحث والتجربة COvid vaccine مثلا مانقدر نصل الى حقيقة فعالية ال

! so we have to ! ايضا مثلا اذا لم نستطع ان نصل الى حل الا من خلاله

مهمة جدا في الناحية التطبيقية لتجنب الحوادث الفضيعة ومانقدر لا من خلال وجود رؤية Ethical Requirements:

لمنظومة البحث والنظر الى متطلبات البحث

! المصدقية فعل اساسي فمن غير المنطقي نطبق البحث على الناس وهو ليست لديه قيمة علمية : 1-scientific value

باختصار استخدام طريقة سليمة وعلمية عند اجراء البحث / يمكن تكون الفكرة جميلة واخلاقية ولكن : 2-scientific validity

تطبيقها خاطئ وغير اخلاقيه

3-fair subject selection: اختيار الانسب بناء على الناحية العلمية

4-Favorable risk-benefit ratio :

. اي اجراء طبي او بحث جديد له مصالح ومضار فبالتالي نوازن ونقلل الاضرار قدر الامكان

بعض الاطباء يغير دواء مريضة بدون علمه او يهدد المريض اذا ماوافق ويقول له لا تجي عيادتي : 5-informed consent

: (من زينها عاد المهم) او انه يكذب عليهم ويقول انه مثبت علميا والصحيح كالتالي

( informed consent ) اعطي المعلومات كاملة و اتأكد ان الشخص فهمها واعطى بعدها الاذن بالموافقة

## Leaders



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**Homoud algadib**

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