ETHICS OF BIOMEDICAL RESEARCH: ISLAMIC PERSPECTIVES

Objectives:

- Appreciate of the importance of ethics in research
- Understand the principles of research ethics
- Appreciate the ethical requirements of research

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Resources:

• 436 Lecture Slides + Notes

Important – Notes

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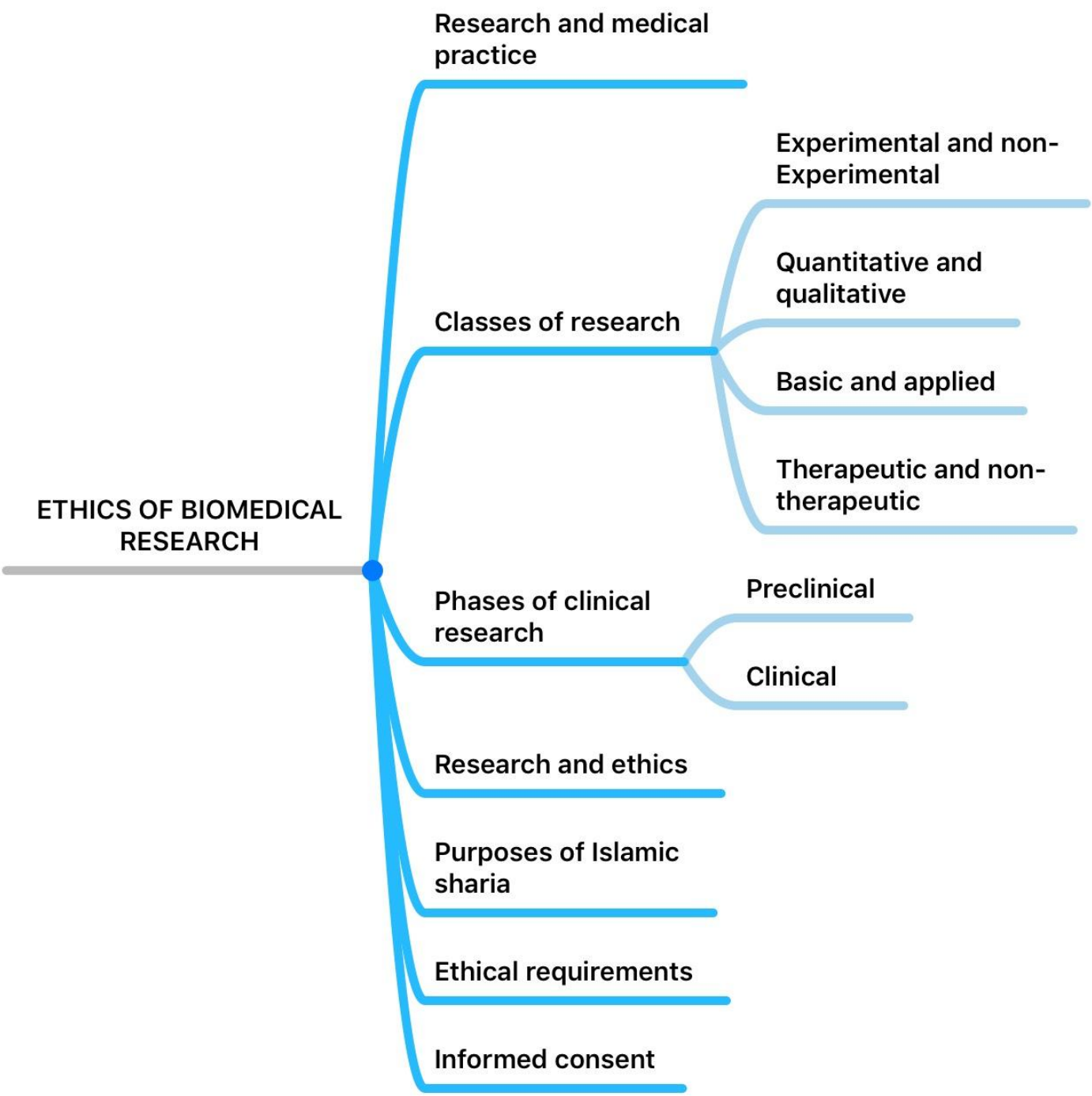
Editing file

Feedback link

Lecture Outline



WHAT IS RESEARCH?

- Careful study of a given subject
- A process to discover new knowledge

RESEARCH AND MEDICAL PRACTICE:

الفرق الأساسي بينهم ان الريسيرش يحتاج ضوابط أكثر لأن فيه استغلال لحاجة المرضى
لذلك يجب التفريق بينهم ، أبلغ المريض انو this is research not current practice

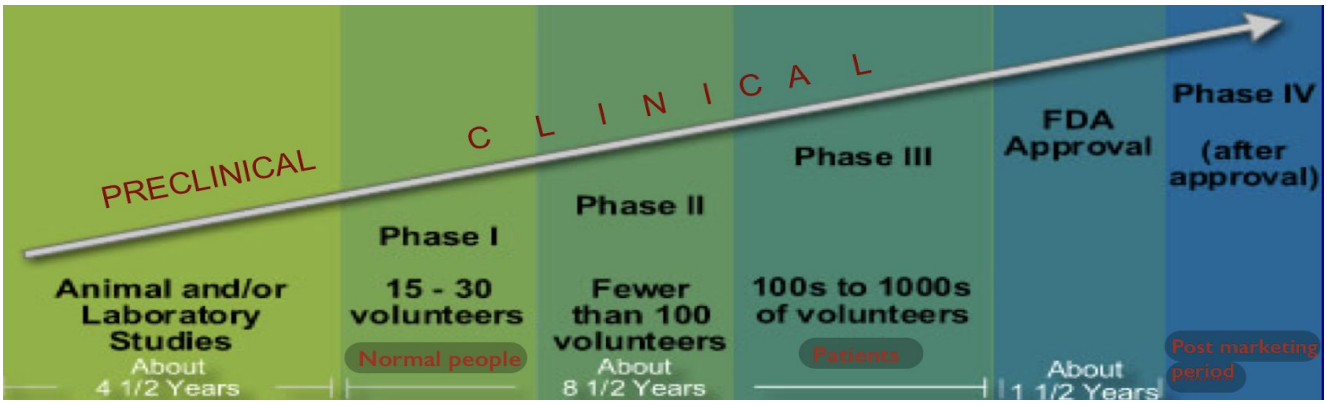
- **Research:**
  - A class of activities designed to develop or contribute to generalizable knowledge
  - A careful and detailed study into a specific problem, concern, or issue using the scientific method
- **Practice:**
  - A class of activities designed soleley to enhance the wellbeing of individual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

CLASSES OF RESEARCH:

هم الأساس experimental and non experimental

- Experimental
- Non-experimental
- Qualitative new type especially in medical field, we don't end up with numbers, ex : ideas , attitude
- Quantitative
- Basic
- Applied
- Therapeutic " clinical research " in this type we have some assumption that the patient will benefit from it
- Non-therapeutic " clinical research and has more ethical considerations " التحرز والضوابط أكثر هنا

PHASES OF CLINICAL RESEARCH: preclinical on animals , once we start doing it on humans we call it clinical .



-Tolerability -Pharmacokinetics -Pharmacodynamics	-Effectiveness -Dosage -Safety	-Comparison -Effectiveness -Side effects	-Comparison -Side effects

أهم مرحلة

WHY BOTHER ABOUT ETHICS IN RESEARCH ?

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

- متى نقول فكرة البحث هذا غير أخلاقية ؟ في حالتين : 1- يكون شي محرم شرعا مثل تجريب المخدرات على الناس ، 2- يكون شي ضرره واااضح مثل تجريب المواد المشعة .

Horrendous experiments: تجاوزات في البحوث الطبية

- Prisoners of war
- Tuskegee syphilis study: 1932-1972

NUREMBERGE CODE

- Informed consent (respect of human)
- Qualified researcher
- Appropriate research design
- Favorable risk/benefit ratio (beneficence)
- Participant freedom to stop (justice)

The belmont report 1978:

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SOURCES OF RESEARCH ETHICS:

دينية وفلسفية

GENERAL ISLAMIC PRICIPLES RELATED TO RESEARCH ETHICS

- Devotional purposes	**أولاً : تحقيق الجانب الايماني والقصد التبعدي**
- Purposes of the law	**ثانياً : تحقيق وحفظ مقاصد الشريعة الإسلاميه**
- Best interest	**ثالثاً: تحقيق المصلحة**
- Preventing and eliminating harm	**رابعاً :دفع الضرر ورفعه**
- Consequences	**خامساً :تقدير المآلات** معرفة ما ستؤول اليه الأمور
- Protecting rights	**سادساً:حفظ الحقوق**
- Duty of care and caring	**سابعاً :تحقيق واجب الرعاية**
- Observing Moral principles and virtues	**ثامناً :قواعد أخلاقية يجب مراعاتها**
- Good treatment/dealing withpeople	**تاسعاً :حسن الخلق في التعامل مع الناس**
- Observing Fighi Principles	**عاشراً : مراعاة القواعد الفقهيه**

- **Is research halal or haram?**

  Every thing is permissible…. الأصل في الأشياء الإباحة

- **Is it oblgatory ?**

مالايتم الواجب إلا به فهو واجب فرض كفاية

If an obligation cannot be completed except with something,that (something) become obligatory

- **Two major principles**

The accruement of benefits + The warding off of harm

- **Five grand principles:**

1. Intent is All-important in action الأمور بمقاصدها
2. ertainty cannot be removed by doubt اليقين لا يزول بالشك
3. hardship engenders facilitation المشقة تجلب التيسير
4. harm should be removed لا ضرر ولا ضرار
5. Custom is the rule العادة محكمة

"You all a shepherd who is responsible for all of his herd”

- **Purposes of islamic sharea**
  1. Protection of religion
  2. Protection of human life
  3. Protection of the mind
  4. Protection of progeny
  5. Protection of property

- **The care Principle**

"You all a shepherd who is responsible for all of his herd”

“كلكم راعٍ وكلكم مسؤول عن رعيته".

Research ethics guidelines and regulations:

European	International
- Convention on Human Rights and Biomedicine, Council of Europe. - Explanation to Convention on Human Rights and Biomedicine. - Convention on Data Protection, Council of Europe. - Data Protection Directive, European Union. - Directive on good clinical practice in the conduct of clinical trials, EU. - Nuffield Council Report. - European Group Ethics: Ethical Aspects of Clinical Research in Developing Countries. - Ethical Conduct for Research Involving Humans.	- WHO Good Clinical Practice Guidelines - ICH Good Clinical Practice - ICH Guidelines on control groups - TDR Operational Guidelines for Ethics Committees - UNAIDS Guidance Document on HIV vaccine trials - **CIOMS GUIDELINES**
Others	**US**
- Ethical guidelines for Biomedical Research on Human Subjects of the Indian Council of Medical Research - Canada's Tri-Council's Policy Statement	- Belmont Report - US Federal Guidelines - NBAC report: Ethical and policy issues in international research: Clinical trials in developing countries

ETHICAL REQUIREMENTS:

- **Scientific Value:**

  1. Responsible use of finite resources
  2. Avoidance of exploitation
  3. Not to expose human being to potential harms without some possible social or scientific benefit
  4. Prioritization

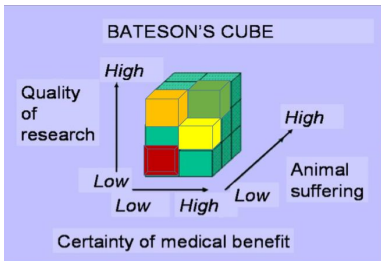
- **Scientific validity:** نقصد فيها المصداقية وتعني اني استخدم الطرق والوسائل الصحيحة اللي توصلني للاوبجيكتفز

  Use accepted scientific principles and methods to produce reliable and valid data.

- **Respect of Potential and enrolled subjects.** نقطة مهمة جدا , كل المشاركين يجب احترامهم في كل الخطوات

  1. Protecting privacy
  2. New risks or benefits
  3. Result of clinical research
  4. Maintaining welfare of subjects
  5. Autonomy and rights
  6. Permitting withdrawal

- **Favourable risk-benefit ratio**



1. Minimizing Risk
2. Enhancement of Potential benefits
3. "Non- Maleficence , Beneficence"

- **Fair subject selection:**
- Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research.
    - Justice

- **Observance of sharia principles and law** "المفروض يكون الشخص على علم بأنظمة البلد"
- **Independent review**
    - Proposed subject population
    - Review design
    - Risk – Benefit Ratio
    - "Conflict of interest"
- **Observance of the local laws/policies**
- **informed consent** نعلمه بكل التفاصيل الصحيحة الدقيقة بدون كذب او خداع بعدها نأخذ اذنه وبنفس الوقت يوافق وهو غير مكره

"NO ONE IS ALLOWED TO ACT UPON THE PROPERTY OF AN INDIVIDUAL UNLESS HE TAKES HIS PERMISSION"

· Informed consent is consent given by a competent individual who received the necessary information, who has adequately understood the information, and who after considering the information, has arrived at a decision without been subject to coercion, undue influence or inducement or intimidation. "Guidelines for CIOMS"

· 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

1. information
2. Understanding/comprehension
3. Consent/voluntariness

Conditions of informed consent:

1. Right
2. Cognizance
3. Capacity
4. Voluntaireness
5. Lawfull procedure

- **Elements of informed consent (IC)**

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 of (IC)

- Unforeseeable risks
- Termination of participation
- Additional costs
- Consequences of withdrawal
- Significant new findings
- Number of participants

IC 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

- **The researcher virtues**
  1. Sincerity/faithfulness
  2. Observance of allah
  3. Integrity/honesty

- **Integrity/honesty**
  - Originality of the study
  - Review of previous studies
  - Truthfulness about the benefits & risks
  - Scientific capability
  - Scientific integrity
  - Impartiality
  - Apporoe research team
  - Observing rights of collaborators

- **Research on special (vulnerable) groups**

A “vulnerable participant” is any individual who lacks the ability to fully consent to participate in a study.

- **Types of vulnerability**

- Physical
- Social
- Cognitive/communicative
- Economic
- Institutional

THE END