03

ETHICS IN MEDICAL RESEARCH(1)

KSU COLLEGE OF MEDICINE
2019 - 2020

ACKNOWLEDGMENTS

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ISLAMIC PERSPECTIVE

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LECTURE **OBJECTIVES**

By the end of this lecture, I am able to:

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

RESEARCH

Definition

Careful study of a given subject. A process to discover new, generalizable knowledge.

In 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.
Medical Practice	A class of activities designed solely to enhance the wellbeing of individual patient. Diagnosis, preventive treatment, or therapy.

Classes Of Research

- Experimental
- Non-Experimental
- Quantitative
- Therapeutic
- Non-Therapeutic
- Qualitative
- Basic
- Applied

These are the clinical research. ethics are mainly concerned with this type. With the none therapeutic having more consideration science it doesn't provide anything to the patient.

Phases Of Clinical Research

	Preclinical	**Clinical**				
Phase	**Animal And/Or Laboratory Studies**	**Phase I**	**Phase II**	**Phase III**	**FDA Approval**	**Phase IV**
Duration	≈ 4 ½ Years		≈ 8 ½ Years		≈ 1 ½ Year	
Participants	Inapplicable	15-30 Volunteer	< 100 Volunteers	100s-1000s Volunteers		After Approval
	In Vivo & Vetro	Normal people	Patients			Post Marketing Period
Notes	• Tolerability • Pharmacokinetics • Pharmacodynamics		• Effectiveness • Dosage • Safety	• Comparison • Effectiveness • Side effects	• Comparison • Side effects	

RESEARCH AND ETHICS

Why Ethics?

- 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
- It is important to have strict ethical guidelines when it comes to research, because, unlike practice, the main goal of research is not the well-being of the patient.

Horrendous Experiments

- **Prisoners Of War:** Some horrendous experiments happened in the past on prisoners during world war 2 who didn't have the right to refuse. Later, the Americans held a trial on them that was called Nuremberg Trial. Read More.
- **Tuskegee Syphilis Study:** A research was done on around 400 african people with syphilis where they were not treated for 40 years to test the natural course of the disease. Read More.
- **Example Of Unethical Practice:** Years ago, a surgery was heavily promoted as a solution for obesity. That surgery was still under experimentation, had very minimal results on weight loss, and included multiple side effects. The main side effect was the inability of undergoing any other weight loss surgery, and that wasn't explained to the patients, which was very unethical.

Nuremberg Code

- Informed consent
- Qualified researcher
- Appropriate research design
- Favorable risk\benefit ratio
- Participant freedom to stop

Read More

The Belmont Report

- Informed consent (respect of human)
- Favorable risk/benefit ratio (beneficence)
- Participant freedom to stop and subject selection (justice)

Read More

SOURCES OF RESEARCH ETHICS

General Islamic Principles Related To Research Ethics

Devotional purposes	تحقيق الجانب الإيماني والقصد التعبدي
Purposes of the law	تحقيق وحفظ مقاصد الشريعة الإسلامية
Best interest	تحقيق المصلحة
Preventing and eliminating harm	دفع الضرر ورفعه
Consequences	تقدير المآلات (معرفة ما ستؤول إليه الأمور)
Protecting rights	حفظ الحقوق
Duty of care and caring	تحقيق واجب الرعاية
Observing Moral principles and virtues	قواعد أخلاقية يجب مراعاتها
Good treatment/dealing with people	حسن الخلق في التعامل مع الناس
Observing Fighi Principles	مراعاة القواعد الفقهية

Purposes Of Islamic Sharia

Protection of religion	حفظ الدين
Protection of human life	حفظ النفس
Protection of the mind	حفظ العقل
Protection of progeny	حفظ العرض
Protection of property	حفظ المال

Five Grand Principles

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

Two Major Principles

The accruement of benefits	جلب المصالح
The warding off of harm	درء المفاسد

Is Research Halal Or Haram?

Everything is permissible — الأصل في الأشياء الإباحة

Is Research Obligatory?

If an *obligation* cannot be completed except with *something*, that *something* become *obligatory* — ما لا يتم الواجب إلا به فهو فرض كفاية

The Care Principle

"You all a shepherd who is responsible for all of his herd." — كلكم راعٍ وكلكم مسؤول عن رعيته.

Guidelines & Regulations

European	US
• Human Rights and Biomedicine Convention, Council of Europe. • Explanation to Convention on Human Rights and Biomedicine. • Data Protection Convention, Council of Europe. • Data Protection Directive, European Union. • Directive on good clinical practice in the conduct of clinical trials, EU. • Nuffield Council Report. • Ethical Aspects of Clinical Research in Developing Countries. • Ethical Conduct for Research Involving Humans.	• Belmont Report. • US Federal Guidelines. • NBAC report: Ethical and policy issues in international research: Clinical trials in developing countries.
International	**Others**
• 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. Read More. • There are so many research guidelines. most of the principles are agreed on among everyone. • In particular, cioms guidelines are discussed in the islamic world by islamic scholars and was supported in the islamic community.	• Ethical guidelines for Biomedical Research on Human Subjects of the Indian Council of Medical Research. • Canada's Tri-Council Policy Statement.

ETHICAL **REQUIREMENTS**

Ethical Requirements

- Scientific value
- Scientific validity
- Respect of potential and enrolled subjects.
- Favourable risk-benefit ratio
- Fair subject selection
- Independent review
- informed consent
- Observance of sharia principles and law
- Observance of the local laws/policies

Scientific Value

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

Making sure the research is important, useful, and not just a waste of resources

Scientific Validity

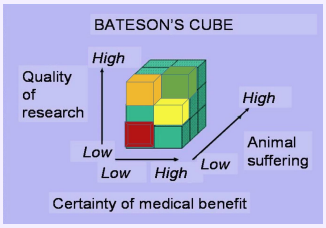
Use accepted scientific principles and methods to produce reliable and valid data.

Fair Subject Selection

Selection of subjects so that stigmatized and vulnerable individuals are not targeted for risky research (Justice). Based on scientific criteria.

Favorable Risk-Benefit Ratio

- Minimizing Risk (Non-Maleficence)
- Enhancement of Potential benefits (Beneficence)



Respect For Subjects

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

Informed Consent

No one is allowed to act upon the property of an individual unless they take their permission.

لا يجوز لأحد التصرف في ملك الغير إلا بإذنه.

- 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.
- 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.

It requires: 1. Information 2. Understanding/Comprehension 3. Consent/Voluntariness

Conditions Of Informed Consent

- Right
- Cognizance
- Capacity
- Lawful Procedure
- Voluntariness

- أن يكون الإذن صادرا ممن له الحق
- أن يعطي الإذن وهو على بينة وإدراك البصيرة
- أن يكون الآذن أهلا للإذن - والأهلية تعتبر بوجود أمرين: البلوغ والعقل
- أن يكون الإجراء مأذون به شرعا
- الاختيار وعدم الإكراه

ELEMENTS OF **INFORMED CONSENT**

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

Volunteer has to know all the honests information without deception. he has to understand that this is an experiment and not part of the treatment. and he must willingly agree without external pressure

Additional Elements

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

Readability

- **Language:** Explanations/Interpretations are simple, and in the participant's language
- **Legibility**
- **Avoid medical jargon** (Terminology)

Waiver Of Informed Consent

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

Waiver Example

FINAL POINTS

1. Observance Of Shari'a Principles & Laws
2. Observance Of Local Laws & Policies
3. Independent Review
   - Proposed subject population
   - Review design
   - Risk–Benefit Ratio
   - Conflict of interest
4. Researcher Virtues
   - Sincerity & Faithfulness
   - Observance Of Allah
   - Integrity & Honesty
5. Integrity & Honesty
   - Originality of the study
   - Review of previous studies
   - Truthfulness about the benefits & risks
   - Scientific capability
   - Scientific integrity
   - Impartiality
   - Appropriate research team
   - Observing rights of collaborators
6. Research On Vulnerable (Special) Groups
   - Any individual who lacks the ability to fully consent to participate in a study, all must be protected and not exploited.
   - **Vulnerable groups:** Elderly, children, disabled, prisoners, mental illness, and poverty.
7. Types Of Vulnerability
   - Physical
   - Social
   - Cognitive/Communicative
   - Economic
   - Institutional