ETHICS OF BIOMEDICAL RESEARCH: ISLAMIC PERSPECTIVES

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“THE VALUE OF RESEARCH DEPEND AS MUCH ON ITS ETHICAL VERACITY AS ON THE NOVELTY OF ITS DISCOVERIES”

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IDEA ➔ PUBLICATION
"The best of people are those that bring most benefit to the rest of mankind."

Prophet Mohammad, PBUH.
WE WANT TO:

- APPRECIATE OF THE IMPORTANCE OF ETHICS IN RESEARCH
- UNDERSTAND THE PRINCIPLES OF RESEARCH ETHICS
- APPRECIATE THE ETHICAL REQUIREMENTS OF RESEARCH
WHAT IS RESEARCH?

CAREFUL STUDY OF A GIVEN SUBJECT

A PROCESS TO DISCOVER NEW KNOWLEDGE
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 soleley to enhance the wellbeing of individual patient. Diagnosis, preventive treatment or therapy.
CLASSES OF RESEARCH
RESEARCH

EXPERIMENTAL

NON-EXPERIMENTAL
RESEARCH

QUANTITATIVE

QUALITATIVE
RESEARCH

BASIC

APPLIED
CLINICAL
RESEARCH

THERAPEUTIC

NON-THERAPEUTIC
PHASES OF CLINICAL RESEARCH
RESEARCH AND ETHICS
WHY BOTHER ABOUT ETHICS IN RESEARCH?
WHY?

- 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
HORRENDOUS EXPERIEMENTS
Prisoners of war
تجاوزات في البحوث الطبية

جوزيف مينغل
Josef Mengele

بسبب حقوقه ضابطاً في الجيش الألماني إضافة لكونه طبيباً فازياً فإنه على الأرجح اسم الأحمر الشهرة في هذه القائمة.

اشتهر الدكتور مينغل بـ"ملاك الموت" كما لقب أيضاً بـ"الشيطان الجميل". وكان مفكراً بوضع تقارير عن السجناء لحشد فيها أي منهم هو الأصح للبقاء على قيد الحياة ليُستعمل ومن هو في غاية الضعف ليتم إعدامه.

لم يكن عمله هذا في تحديد مصير ملايين الناس هو السبب في انتشار صيته فقط بل إن هناك أمرأً آخر لعب دور الهام في شهرته الكبيرة خلال التاريخ، حيث ثبت إجرااؤه تجارب على البشر.

أجرى الدكتور مينغل تجارباً جنونية في مختبر أوسوينتري حيث أجري مختبر جراحه مع دارسة الوراثة وطالما أنه أجرى تجارب على الايئون المتالكية. وقائل بأنه أخذ عشرة ثوان وقام بتخديرهم ومن ثم فقتهم مستخدماً الكلوروفورم، وعند يقوم بتخريج كل واحد منهم لجيري مقارنة بين اسهامهم.

وطبب أن قال بصنع تواتم ملونة ملونة بربط أوردة معاً بعضها البعض، ولم يكن الدكتور مينغل.

يدل محل فلد أيضاً تجارباً آخر في الأحمر جنوناً صناعي لون العينين بحن الصياح داخل القفصية، والقيام ببدن الأطراف ثم محاولة وصلها بالجسم من جديد.
NUREMBERGE CODE

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

CONTINUED FOR HOW LONG?
1932-1972
RESPECT OF HUMAN
INFORMED CONSENT

BENEFICENCE........BENEFIT/RISK

JUSTICE ... SUBJECTS SELECTION
SOURCES OF RESEARCH
ETHICS
IS RESEARCH HALAL OR HARAM?
GENERAL ISLAMIC PRINCIPLES RELATED TO RESEARCH ETHICS

- Devotional purposes
- Purposes of the law
- Best interest
- Preventing and eliminating harm
- Consequences
- Protecting rights
- Duty of care and caring
- Observing Moral principles and virtues
- Good treatment/dealing with people
- Observing Fighi Principles

أولاً: تحقيق الجانب الإيماني والقصد التبعدي
ثانياً: تحقيق وحفظ مقاصد الشريعة الإسلامية
ثالثاً: تحقيق المصلحة
رابعاً: دفع الضرر ورفعه
خامساً: تقدير الماليات
سادساً: حفظ الحقوق
سابعاً: تحقيق واجب الرعاية
ثامناً: قواعد أخلاقية يجب مراعاتها
تاسعاً: حسن الخلق في التعامل مع الناس
عاشراً: مراعاة القواعد الفقهية
PURPOSES OF ISLAMIC SHAREA

- PROTECTION OF RELIGION
- PROTECTION OF HUMAN LIFE
- PROTECTION OF THE MIND
- PROTECTION OF PROGENY
- PROTECTION OF PROPERTY
IS RESEARCH HALAL OR HARAM?

EVERY THING IS PERMISSIBLE....
الأصل في الأشياء الإباحة
IS IT OBLIGATORY?

مااليتم 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

INTENT IS ALL-IMPORTANT IN ACTION

CERTAINTY CANNOT BE REMOVED BY DOUBT

HARSHSHIP ENGENDERS FACILITATION

HARM SHOULD BE REMOVED

CUSTOM IS THE RULE
The care Principle

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

كلكم راع وكلكم مسؤول عن رعيته
Research ethics guidelines and regulations
International

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
European

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
US
Belmont Report
US Federal Guidelines
NBAC report: Ethical and policy issues in international research: Clinical trials in developing countries

Others
Ethical guidelines for Biomedical Research on Human Subjects of the Indian Council of Medical Research
Canada's Tri-Council's Policy Statement
ARE THESE ISLAMIC?
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
ETHICAL REQUIREMENTS

SCIENTIFIC VALUE:

- Responsible use of finite resources
- Avoidance of exploitation
- Not to expose human being to potential harms without some possible social or scientific benefit
- Prioritization

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)

FAVOURABLE RISK – BENEFIT RATIO

- Minimizing Risk
- Enhancement of Potential benefits
- “Non-Maleficence, Beneficence”
BATESON’S CUBE

Quality of research

Low  High

Low  Low  High

Certainty of medical benefit

High  Low

Animal suffering
RESPECT FOR SUBJECTS

- Permitting withdrawal

- Protecting privacy
- New risks or benefits
- Result of clinical research
- Maintaining welfare of subjects
  - “Autonomy and rights”

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

- 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
INFORMED CONSENT

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.
INFORMED CONSENT

- INFORMATION

- UNDERSTANDING/COMPREHENSION

- CONSENT/VOULTAIRNESS
شروط الاذن

CONDITIONS OF INFORMED
CONSENT

أن يكون الإذن صادراً ممن له الحق,

RIGHT

أن يعطي الإذن وهو على بيئة

COGNIZANCE

الاختيار، وعدم الإكراه

VOLUNTARENESS

أن يكون الاذن أهلاً للإذن والأهلية

CAPACITY

لا يكون الإجراء مأذون بها شرعاً

LAWFULL PROCEEDURE

تعتبر بوجود أمرين أحدهما:

البلوغ والثاني العقل
“The biggest risk in this study is just reading the consent form!”
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
ESSENTIAL ELEMENTS

- Assurance of confidentiality
- A statement about compensation
- Contact details
- Assurance of voluntariness of participation
ADDITIONAL ELEMENTS

- Unforseeable risks
- Termination of participation
- Additional costs
- Consequences of withdrawal
- Significant new findings
- Number of participants
IC READIBILITY

- **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
Observance of sharia principles and law

- INDEPENDENT REVIEW
  - Proposed subject population
  - Review design
  - Risk – Benefit Ratio
    - “Conflict of interest”

Observance of the local laws/policies
اللائحة التنفيذية لنظام أخلاقيات البحث على المخلوقات الحية
THE RESEARCHER VIRTUES

SINCERITY/FAITHFULNESS

OBSERVANCE OF ALLAH

INTEGRITY/HONESTY
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
RESEARCH ON SPECIAL VULNERABLE GROUPS

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

http://www.virginia.edu/vpr/irb/sbs/resources_guide_participants_vuln.html
VULNERABLE GROUPS
Types of vulnerability

- PHYSICAL
- SOCIAL
- COGNITIVE/COMMUNICATIVE
- ECONOMIC
- INSTITUTIONAL
Thank You