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”

WILLMAN,2011,P: 267

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

CONTENT

- RESEARCH .. AND... PRACTICE..A DISTINCTION
- RESEARCH AND ..ETHICS

- SOURCES OF RESEARCH ETHICS
  - ISLAMIC SOURCES/ PRICIPLES
  - OTHER SOURCES
- ETHICAL REQUIREMENTS OF RESEARCH

- ETHICS RELATED TO THE RESEARCHER
- CONCLUSIONS

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

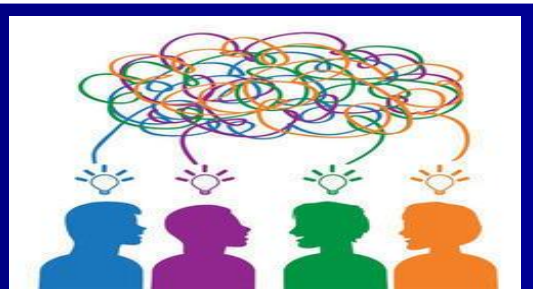
EXPERIMENTAL

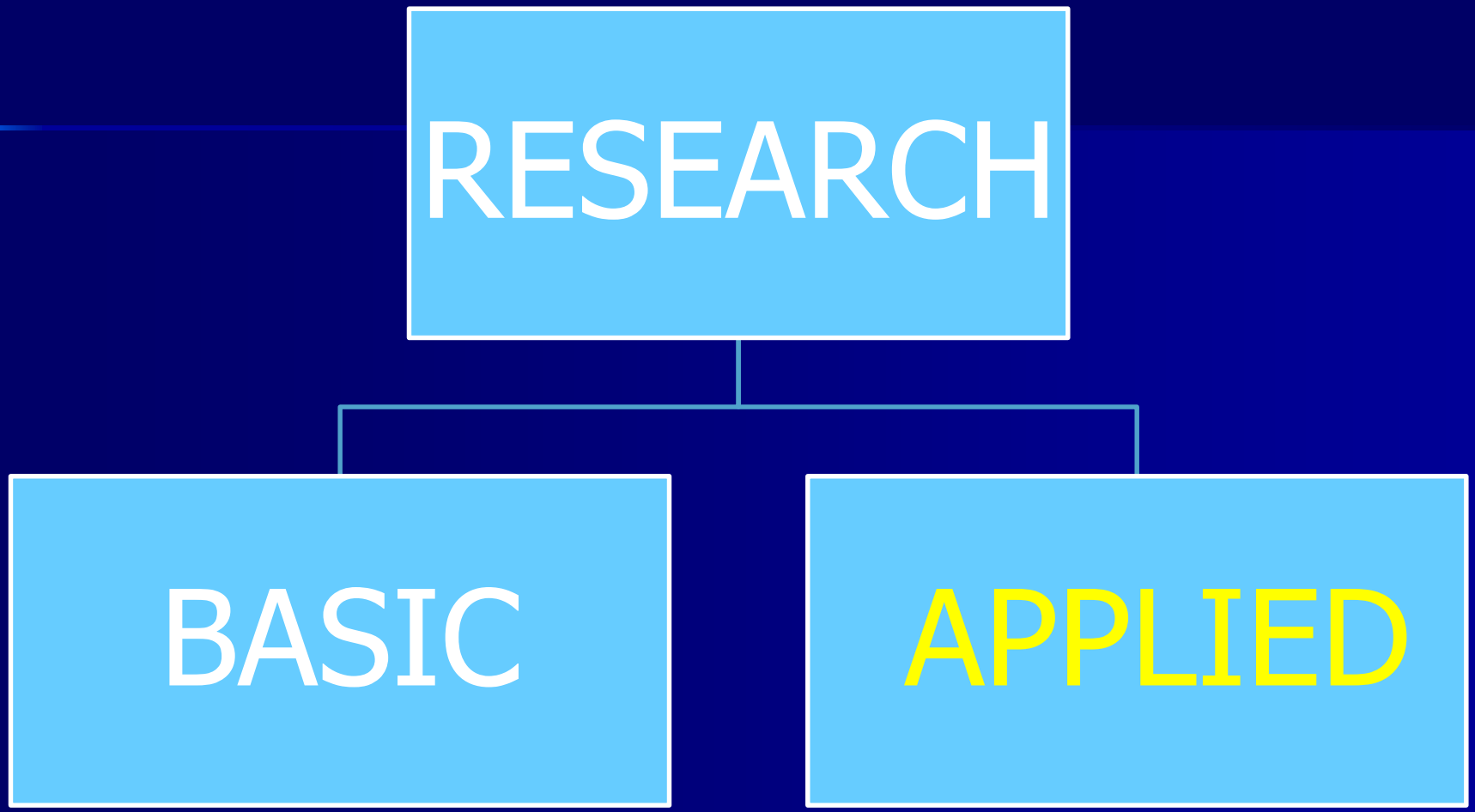
NON-EXPERIMENTAL

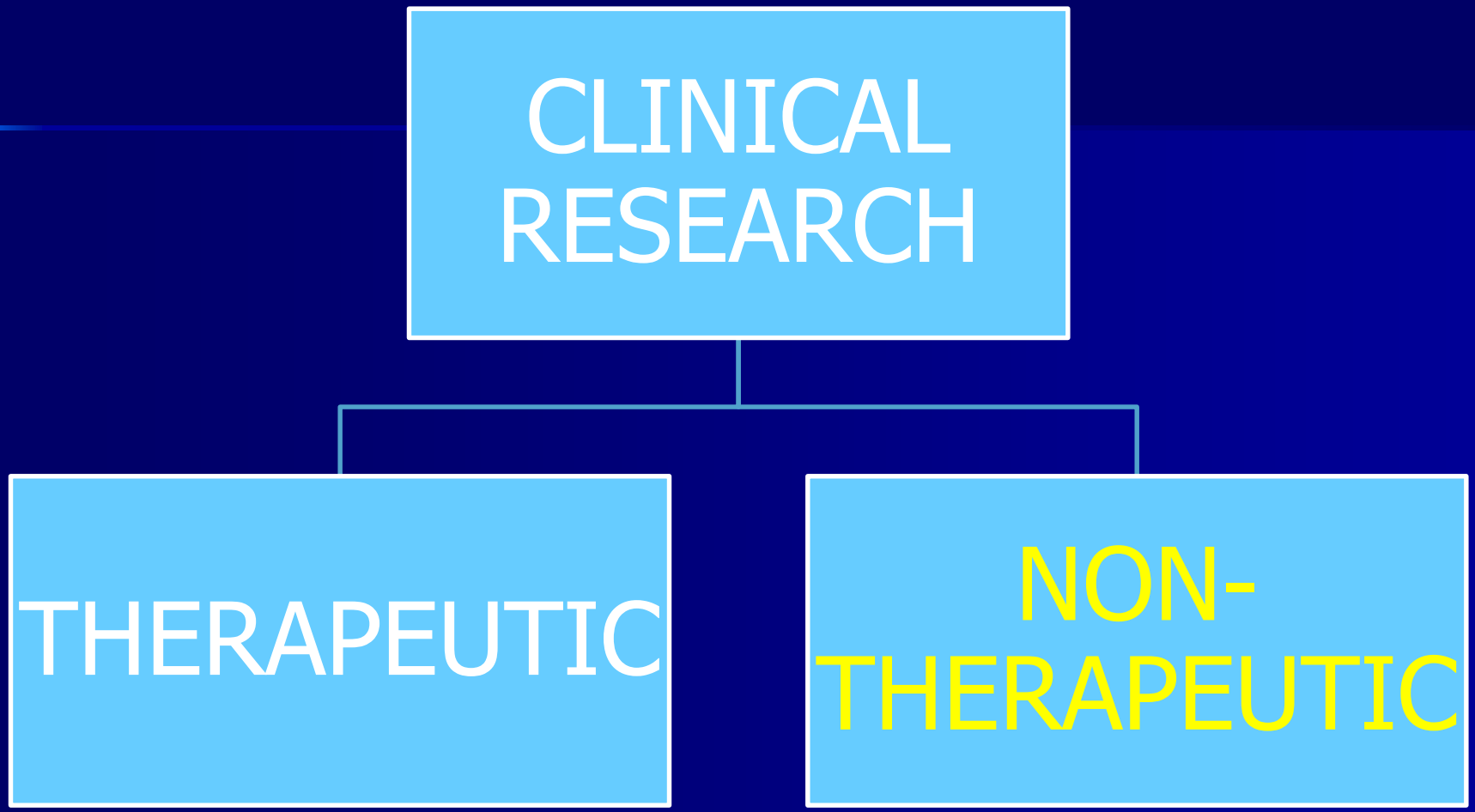
RESEARCH

QUANTITATIVE

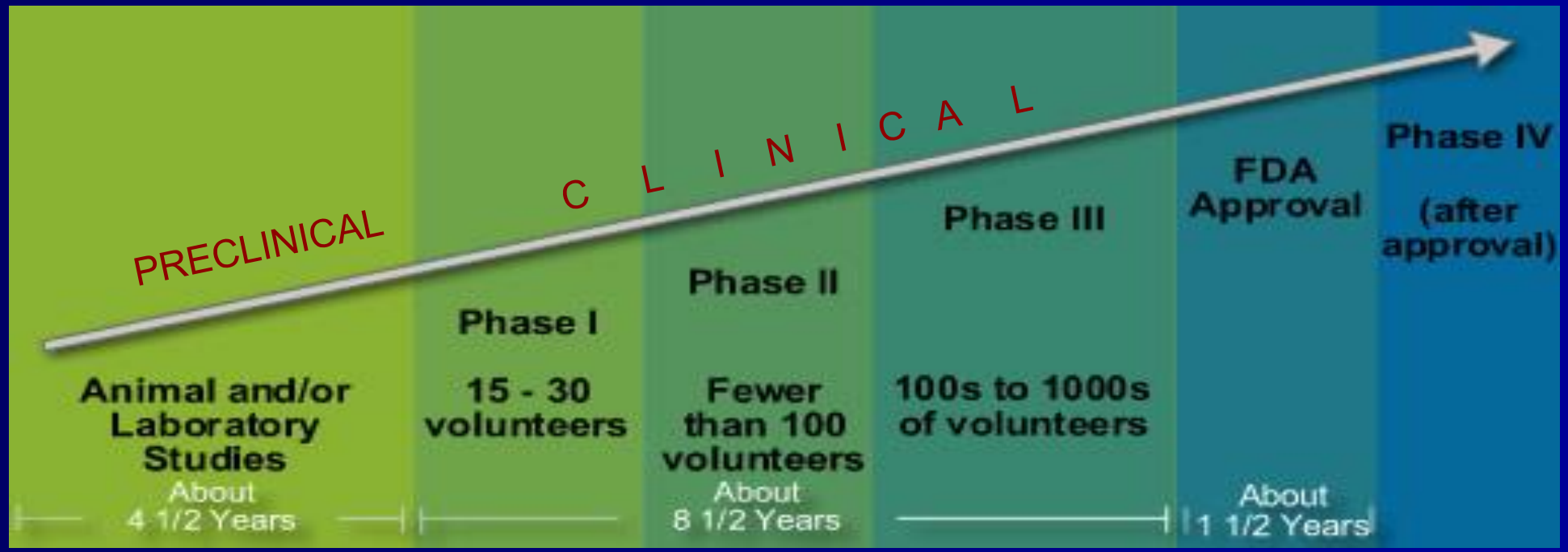
QUALITATIVE




RESEARCH
BASIC
APPLIED


CLINICAL RESEARCH
THERAPEUTIC
NON-THERAPEUTIC

PHASES OF CLINICAL RESEARCH



Tolerability
Pharmacokinetics
Pharmacodynamics

Effectiveness
Dosage, Safety

Comparison
Effectiveness
Side effects

Comparison
Side effects

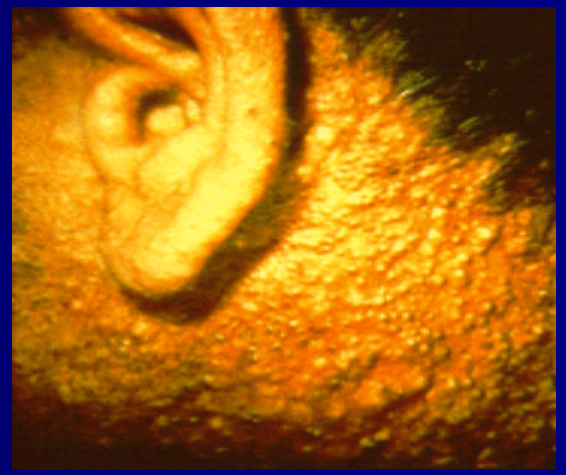
RESEARCH AND ETHICS

WHY BOTHER ABOUT ETHICS IN RESEARCH ?

WHY ?

- PROTECTION OF PARTICIPANTS
- SAFEGAURD AGAINST EXPLOITATION
- ENSURE RESPECT OF INDIVIDUALS, DIGNITY,COFIDENTIALITY AND PRIVACY
- ENSURE GOOD CLINICAL PRACTICE IN RESEARCH
- SAFEGAURD AGAINST VIOLATIONS IN RESARCH AND RESEARCH MISCONDUCT

HORRENDOUS EXPIREMENTS



Prisoners of war

تجاوزات في البحوث الطبية

جوزيف مينغل

Josef Mengele

بسبب كونه ضابطاً في الجيش الألماني إضافة لكونه طبيباً نازياً فإنه على الأرجح الاسم الأكثر شهرة في هذه القائمة.

اشتهر الدكتور مينغل بـ "ملاك الموت" كما لقب أيضاً بـ "الشيطان الجميل"، وكان مكلفاً بوضع تقارير عن السجناء يحدد فيها أي منهم هو الأصلح للبقاء على قيد الحياة ليُستعبد 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 أمراً آخر لعب الدور الهام في شهرته الكبيرة خلال التاريخ، حيث ثبت إجراؤه تجارب على البشر.

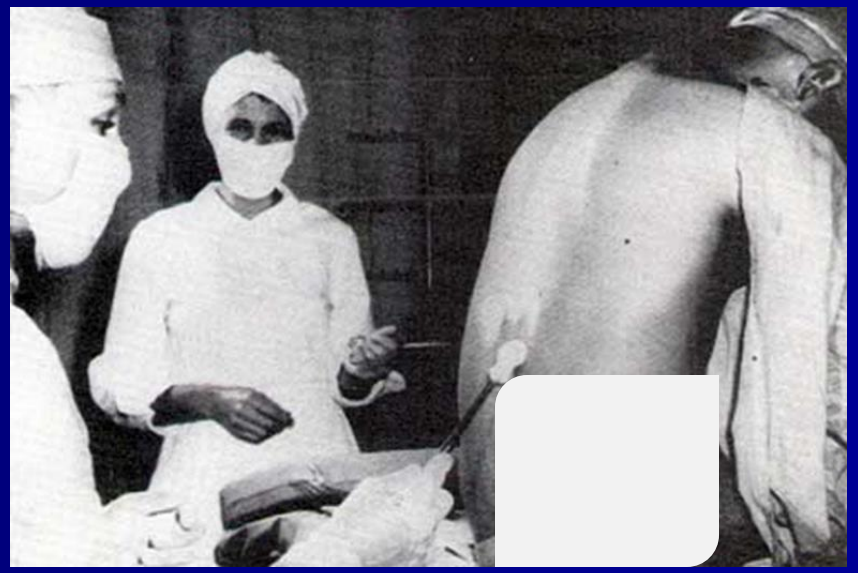
أجرى الدكتور مينغل تجارباً جنونية في مخيم أوشويتز حيث أنه كان مهتماً جداً بدراسة الوراثة وطالما أجرى تجاربه على التوائم المتطابقة. ويقال بأنه أخذ عشرة توائم وقام بتخديرهم ومن ثم قتلهم مستخدماً الكلوروفورم، وأخذ يقوم بتشريح كل واحد منهم ليجري مقارنة بين أجسادهم، كما أنه قام بصناعة توائم ملتصقة بربط أوردتها مع بعضها البعض، ولم يكتف الدكتور مينغل بذلك بل قاد أيضاً تجاربا أخرى هي الأكثر جنوناً كتغيير لون العينين بحقن الصباغ داخل القزحية، والقيام ببتر الأطراف ثم محاولة وصلها بالجسم من جديد..

NUREMBERGE CODE

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

تجاوزات في البحوث الطبية

TUSKEGEE SYPHLIS STUDY

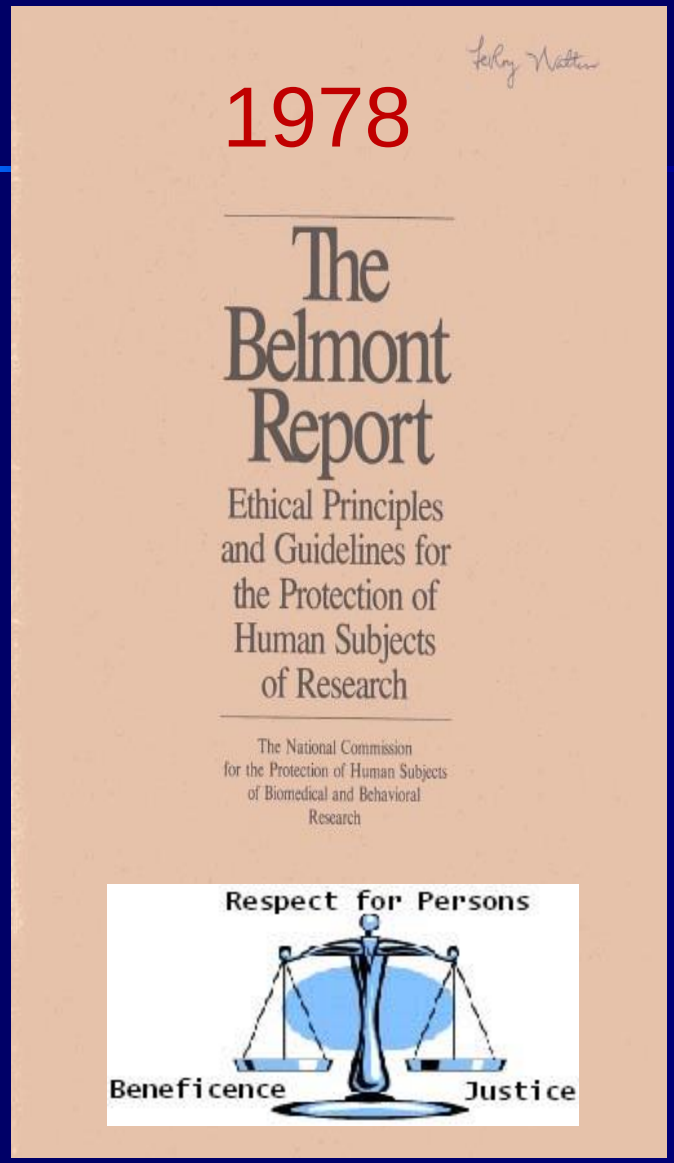


CONTINUED FOR HOW LONG?

1932-1972

1997

1978



RESPECT OF HUMAN
INFORMED CONSENT

BENEFICENCE…….BENEFIT/RISK

JUSTICE … SUBJECTS SELECTION

SOURCES OF RESEARCH ETHICS

IS RESEARCH HALAL OR HARAM?

GENERAL ISLAMIC PRICIPLES 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 withpeople
- Observing Fighi Principles

- أولاً : تحقيق الجانب الايماني والقصد التبعدي
- ثانياً : تحقيق وحفظ مقاصد الشريعة الإسلاميه
- ثالثاً: تحقيق المصلحة
- رابعاً :دفع الضرر ورفعه
- خامساً :تقدير المآلات
- سادساً:حفظ الحقوق
- سابعاً :تحقيق واجب الرعاية
- ثامناً :قواعد أخلاقية يجب مراعاتها
- تاسعاً :حسن الخلق في التعامل مع الناس
- عاشراً : مراعاة القواعد الفقهيه

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 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 جلب المصالح

THE WARDING OFF OF HARM درء المفاسد

FIVE GRAND PRINCIPLES

INTENT IS ALL-IMPORTANT IN ACTION

الأمور بمقاصدها

CERTAINITY CANNOT BE REMOVED BY DOUBT

اليقين لايزول بالشك

HARSHIP ENGENDERS FACILITATION

المشقة تجلب التيسير

HARM SHOULD BE REMOVED

لاضرار ولا ضرار

CUSTOM IS THE RULE

العادة محكمة

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

(*JAMA*. 2000;283(20):2701-2711. doi:10.1001/jama.283.20.2701)

- 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.

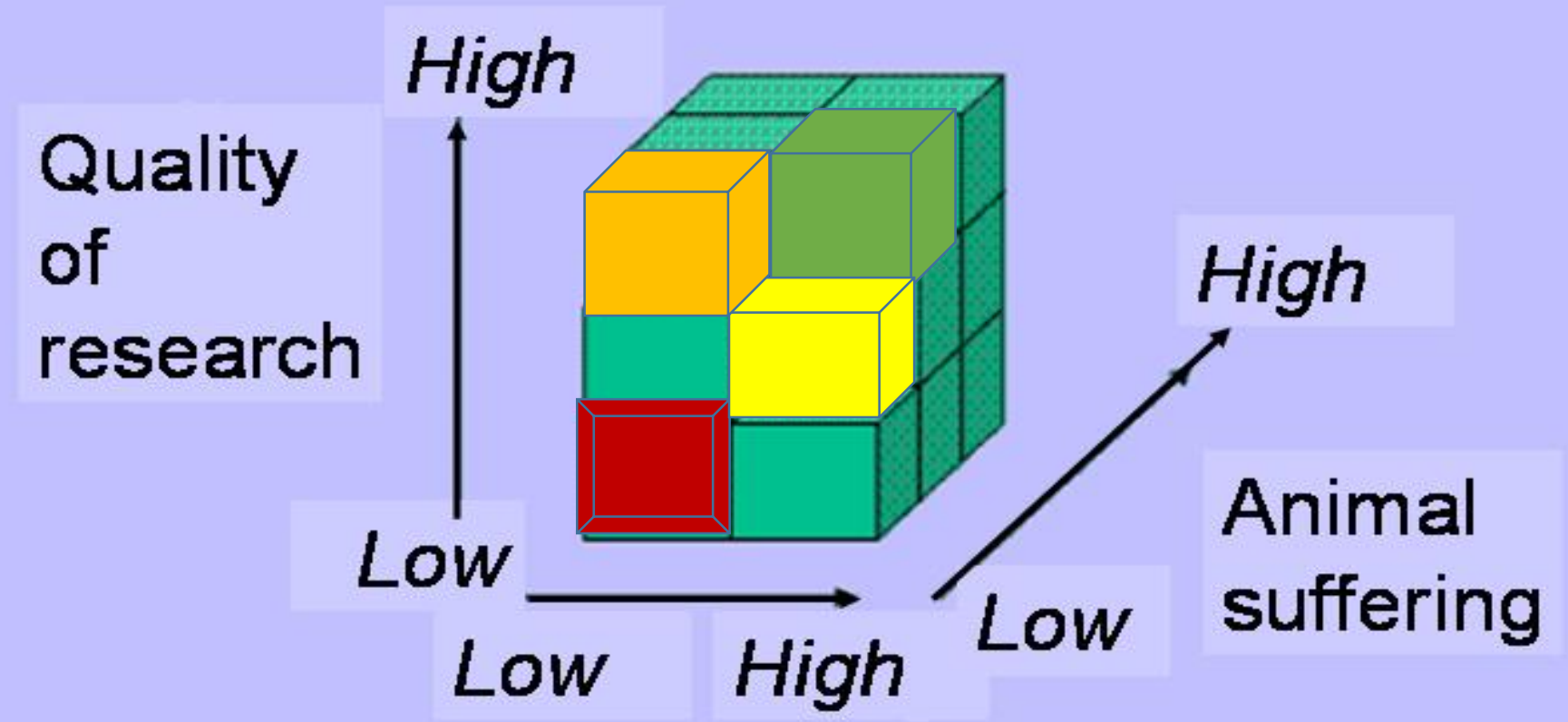
FAIR SUBJECT SELECTION

- Selection of subjects so that stigamatized 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



RESPECT FOR SUBJECTS

- Permitting withdrawal

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

INFORMED CONSENT

”لايجوز لأحد التصرف في ملك الغير إلا بإذنه“

“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 voluntairly 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 الآذن أهلاً للإذن والأهلية تعتبر بوجود أمرين أحدهما: البلوغ والثاني العقل

CAPACITY

أن يعطي الإذن وهو على بينة وإدراك

(البصيرة)

COGNIZANCE

أن يكون الإذن صادراً ممن له الحق,

RIGHT

أن يكون الاجراء مأذون بها شرعا

LAWFULL PROCEEDURE

الاختيار , وعدم الإكراه

VOLUNTAIRENESS

ELEMENTS OF INFORMED CONSENT (IC)

"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 voluntairness of particpation

ADDITIONAL ELEMENTS

- Unforseeable risks
- Termination of participation
- Additional costs
- Consequences of withdrwal
- 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

المملكة العربية السعودية

مدينة الملك عبدالعزيز
للعلوم والتقنية KACST

اللجنة الوطنية للأخلاقيات الحيوية

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
- APPOROPRIATE 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