أساليب البحث

دورة تدريبية

Research Methodology

Training Course

شئون البحث العلمي و الدراسات العليا

Research and postgraduate Affair

أخلاقيات البحث العلمي

Research Ethics

Prof. Dr. Abdelraouf A. Elmanama

Training Course content

	Title	Duration	Speaker	Date & Place
	Opening ceremony افتتاح			
١	Elements of a successful Research Proposal & research ethics – عناصر المقترح البحثي الجيد اخلاقيات البحث العلمي	2 hours	Prof. Abdelraouf A. Elmanama	**Saturday 7-11-2015**
٢	Basic concepts in research & Research Designs – مفاهيم أساسية في البحث العلمي تصميمات البحوث	2 hours	Dr. Khamis Elessi	**Monday 9-11-2015**
٣	Citation & referencing in research الاستدلال والتوثيق في البحث العلمي	2 hours	Prof. Adnan Al-Hindi	**Sunday 15-11-2015**
٤	Evidence Based research - basic concepts البحث العلمي المبنى على الادلة – مفاهيم أساسية	2 hours	Dr. Khamis Elessi	**Tuesday 17-11-2015**
٥	How to enter, clean and analyses research Data ادخال البيانات وتجهيزها وتحليلها	2 hours	Prof. Adnan Al-Hindi	**Saturday 21-11-2015**
٦	How to critique a research article نقد دراسة علمية	2 hours	Prof. Abdelraouf A. Elmanama	**Monday 23-11-2015**
	Certificates ceremony توزيع الشهادات			

What is Ethics

- The study of standards and conducts and moral judgment

- The system or code of morals of a particular person, religion, group, or profession

Principles of Ethical Research

- Respect for Persons احترام الانسان
- Beneficence الفائدة
- Justice العدل

Respect for Persons

- Forms the foundation of participant's right to **informed consent, privacy, & confidentiality**
- Involves respecting **autonomy** or right to choose freely
- Right to be free from pressure or coercion
- Confidentiality & anonymity must be protected
- Must have information to make informed choices (risks vs benefits)

Beneficence

- Non-maleficence - the duty to not inflict harm
- Beneficence - the duty to promote good
- Researcher's responsibility to minimize risk & maximize benefits to participants

Justice

- People ought to be treated fairly
- Protection of participants from incompetence
- Random selection of participants avoids potential bias and unfairness in sample selection

INFORMED CONSENT

- What is it?
- Why do we need it?
- From whom do we get it?
- How do we get it?
- How can we be sure we're doing it right?

- Sufficient & appropriate information
- Comprehension of information
- Voluntary participation
- An invitation to participate rather than an expectation

Informed Consent

- What it is
  - A Process
  - Acknowledging respect for persons (Autonomy)

Goal

- "The goal of the informed consent process is to provide people with sufficient information so they can make informed choices about whether to begin or continue participation in clinical research."

The process

- "...involves a dynamic and continuing exchange of information between the research team and participant throughout the research experience..."

The document

- "...a starting point for the necessary exchange of information between investigator and potential participant."
- "...the foundation not the entirety..."

Why do we need it?

- Respect for persons
- Respect for autonomy of decision making
- True limit on investigative authority
- Sense of formality

Declaration of Helsinki (World Medical Association)

- Articulated ethical principles for use by physicians conducting human research
- Affirmed the autonomy of the individual
- Universally adopted to ensure the rights and welfare of human subjects of research

Belmont Report

- 3 basic principles that should govern all research involving human subjects
  - *Respect for persons*
  - *Beneficence* (maximize benefits, minimize risks, avoid harm)
  - *Justice* (benefits and burdens equally distributed)

What does someone need to know?

- Disclosure (what's going to happen)
- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensation

Are we doing it right?

- Voluntariness:
  - Freely coming to a decision
  - Free from coercion or undue influence
  - Assumes capacity

Vulnerable populations

- Children ?
- Prisoners?
- Mentally retarded individuals
- Dementia/Coma/
- Mental illness
- Pregnant women
- Emergency patients? (pain, fear, etc.)

Vulnerable Populations: Children

- If child can understand (> age 6-8)
  - We are obligated to obtain assent
- Can parents overrule?
  - In studies with more than minimal risk and not without prospect of direct benefit

Other vulnerable populations

- Research on individuals who lack capacity also requires prospect of benefit
- Family member can consent

How do we get informed consent?

- Will vary according to study design and nature of participation
- Verbal vs. Written
- Investigator vs. proxy

Healthy volunteers

- Volunteers may not stand to benefit directly, but could ultimately contribute to development of a new therapy that the participant might then use.
- Require particularly close monitoring, because they can pose a risk to a volunteer's health or life.

Why do people participate in biomedical research?

- Altruism (sacrifice)
- Free medical care and medications
- Trust
- Self-interest
- Attention
- Do we want to constrain people if they are doing things for the wrong reasons?

End of Lecture

Thank you