Professionalism TEAM

Ethics of Medical Research

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431 Teams
medical students

Objectives:

1) Identify the main principles of medical research ethics.
2) Discuss the balance of research and clinical care.
3) Describe requirements of ethics review committees, including definition of informed consent.
4) Identify the key international and national references for the rules and regulations of medical research

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Principles of Research with Human Subjects:

- Respect for Persons
  - ✓ individuals have autonomy and choice
  - ✓ people cannot be used as a means to an provide protection to the vulnerable
  - ✓ provide informed consent and privacy

١. معاملة الإنسان كشخصية مستقلة له رأيه الحر دون إكراه.
٢. الإحسان و منع الإساءة كما يجب أن لا يصيب الضرر الإنسان نتيجة للبحث.
٣. العدل في العبء و الفائدة المرجوة من البحث.

- Beneficence
  - ✓ kindness beyond duty
  - ✓ obligation to do no harm
  - ✓ obligation to prevent harm
  - ✓ obligation to do good
  - ✓ minimize risks, maximize benefits

- Justice
  - ✓ treat all fairly
  - ✓ share equitably burdens and benefits

Research ethics : Declaration of Helsinki (DoH) :

declaration of Helsinki: statement of ethical principles for medical research involving humans

(1) Ethics Review Committee Approval
Medical research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed.

(2) Scientific Merit
Medical research involving human subjects must be justifiable on scientific grounds .

(3) Qualified Researchers :
Medical research involving human subjects must be conducted by qualified researchers.

(4) Social Value
Medical research project should that it contribute to the wellbeing of society in general.

(5) Risks and Benefits
It is also necessary for the researcher to demonstrate that the risks to the research subjects are not unreasonable or disproportionate to the expected benefits of the research, which may not even go to the research subjects.

(6) Informed Consent
The first principle of the Nuremberg Code reads as follows: "**The *voluntary consent of the human subject is absolutely essential*.**"

الموافقة بعد التبصير : إعطاء الشخص موافقته بمطلق حريته دون استغلال أو إكراه ، بعد أن أدرك ما يطلب منه ، وأدرك أهداف البحث واحتمالات الخطر فيه وما يترتب على مشاركته من حقوق وواجبات .

(7) Confidentiality
Research subjects have a right to privacy with regard to their personal health information.

(8) Conflict of Roles
The physician's role in the physician-patient relationship is over the researcher's role,even if the physician and the researcher are the same person.

(9) Honest Reporting of Results
Research results be reported accurately, but unfortunately there have been numerous recent accounts of dishonest practices in the publication of research results.

(10) Whistle-blowing
In order to prevent unethical research from occurring, or to expose it after the fact, anyone who has knowledge of such behaviour has an obligation to disclose this information to the appropriate authorities.

(11) Justice
Equitable selection of participants, i.e., avoiding participant populations that may be unfairly coerced into participating, such as prisoners and institutionalized children. The principle of justice also requires equality in distribution of benefits and burdens among the population group(s) likely to benefit from the research.

Summary for main ethical research requirements :

1. Voluntary consent
2. For good of society
3. Animal experiments 1st; human experiments 2nd
4. Avoid unnecessary suffering
5. Do not conduct if death & debility likely
6. Risk commensurate with benefits
7. Protect subjects against harm
8. Conducted only by qualified persons
9. Subjects should be at liberty to discontinue
10. Terminate if becomes apparent that death or debility will occur

The National Committee of Medical & Bioethics was approved by the Royal Decree on 18/5/1422H, to be headquartered at KACST in Riyadh. It consists of the following sub-committees:

1. The legal sub-committee.
2. The human research sub-committee.
3. The flora & animal sub-committee.
4. The education & media sub-committee .

Examples:

1-Mrs X , an 81-year-old Alzheimer's patient hospitalized under your care has been asked to participate in a clinical trial testing a new drug designed to help improve memory. You were present when the clinical investigator obtained a signed informed consent from Mrs X a few days ago. However, when you visit Mrs. X today and ask her if she is ready to begin the study tomorrow, she looks at you blankly and seems to have no idea what you are talking about.

What should you do?

Answer: The competence of Mrs. X to give an ethically valid informed consent is in doubt. You should contact the primary investigator to discuss Mrs. X ‘s participation in the trial. There may be a surrogate who can give consent for her participation if it is deemed to be in her best interests. Although she may be considered a **vulnerable research subject because of her mental status,** Mrs. X does belong to the population the intervention is designed to assist, and her participation may benefit herselfand other Alzheimer's patients. However, a careful balancing of risks and benefits should occur.

2- After having completed a study that involved the collection of tissue from the subjects, an investigator wishes to perform additional
analysis of the archived tissue samples. This nature of this analysis was not explicitly (صراحه)stated in the original consent form.
Should the investigator be required to obtain explicit consent for the new research?

Answer: Institutional Review Boards (or research committees) have increasingly required that explicit consent be obtained, if practical,
before archived tissue can used for research. Archiving samples for an unspecified "future use" without explicit consent undermines **the autonomy of the participants.** Even if participants may be willing in general to have surplus tissue used for research purposes,
they should still be asked for their consent.