▶RESEARCH ETHICS

- OBJECTIVES

- Describe general ethical principles
- Describe responsibility of ethics in health research
- Describe the functions of review committees (IRB)
- Describe ethical considerations through out the research process
- General principles of Helsinki deceleration

▶WHAT IS RESEARCH ETHICS

Research Ethics is defined as the **ethics** of planning, conduct, and reporting of **research**. It is clear that **research ethics** should include: Protections of human and animal subjects.

▶HUMAN SUBJECTS

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    - **GENERAL ETHICAL PRINCIPLES**

Ethics are principles of right conduct. There are generally no disagreements on the ethical principles in themselves, since they represent basic human values. There can, however, be differences on how they are interpreted and implemented in specific cases. Basic principles include ***beneficence, non-maleficence, respect and justice.***

Beneficence and Non – Maleficence: Where research involves experimentation on human subjects, every effort should be made to maximize the benefits to the subjects

(beneficence), and the subjects should suffer no harm *(non – maleficence).*

Respect: The principle of *respect* implies that participation in the research should be completely voluntary and based on informed consent. Where research involves collection of data on individuals, privacy should be protected by ensuring confidentiality. Respect to the community means respecting its values and having its approval for the research.

Justice: The principle of *justice* (distributive justice) implies that participation in the research should correlate with expected benefits. No population group should carry an undue burden of research for the benefit of another group.

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▶ RESPONSIBILITY OF ETHICS IN HEALTH RESEARCH

Responsibility for ensuring that ethical standards are observed in research rests collectively with the ***investigators, research institutions, national drug regulatory agencies, editors of medical journals, and funding agencies and organizations.***

Ethical approval by one does not relieve the others of responsibility.

- **INVESTIGATORS**

The primary and ultimate responsibility rests with the investigators who should, as a part of their training, be made aware of and sensitive to the ethical imperatives in research. No research protocol is complete or acceptable if it does not discuss the ethical aspects of a study involving human subjects or experimental animals.

- **RESEARCH INSTITUTION**

- The research institution is responsible for the ethical quality of the research performed by its staff and in its facilities.
- Any institution involved in research on human subjects should have an institutional ethics review committee.
- The committee acts as a gathering of the investigators' peers and others to

provide advice on ethical aspects of the study and to approve it or disapprove it on behalf of the institution.

- **RESEARCH INSTITUTION**

- The membership may include other health professionals, particularly nurses, as well as laymen qualified to represent the community's cultural and moral values.

- The committee should be completely independent from the investigators. Any member with a direct interest in a proposal should not participate in its assessment.

- **NATIONAL DRUG REGULATORY AGENCY**

New drugs or devices that are not yet approved in the country should not be used on human subjects without approval being obtained for their use under the conditions of the study.

- EDITORS OF MEDICAL JOURNALS

Reports of research not complying with ethical standards should not be accepted for publication.

FUNDING AGENCIES AND ORGANIZATIONS

No research proposal should be funded by a national or international agency unless it has clearly outlined the ethical aspects of the study and has provided assurances that ethical principles will be observed, including, as appropriate, the approval of an institutional review committee.

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- **ETHICS COMMITTEES**

Countries and institutions should establish ethical review systems to ensure the protection of potential research participants and contribute to the highest attainable quality in the science and ethics of health research. Ethics committees should be established, as appropriate, at the national, regional and institutional levels.

▶ SOME FUNCTIONS OF ETHICAL COMMITTEES

- Ethics committees should be so constituted as to ensure the competent review and evaluation of all

ethical aspects of the research projects they receive and to ensure that their task can be executed free from any bias and influence that could affect their independence.

- Ethics committees should be multidisciplinary and multi-sectoral in composition, including relevant scientific expertise, balanced age and gender distribution, and laypersons representing the interests and concerns of the community.
- Ethics committees should be established in accordance with the applicable laws and regulations of the country and in accordance with the values and principles of the communities they serve.
- Ethics committees should establish publicly available standard operating procedures that state the authority under which the committee is established, the functions and duties

of the committee, membership requirements, the terms of appointment, the conditions of appointment, the offices, the structure of the secretariat, internal procedures and quorum requirements.

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- **ETHICAL CONSIDERATIONS THROUGHOUT THE RESEARCH PROCESS**

The research process begins with the choice of the research topic,

followed by selection of the appropriate research design, development of the research protocol, writing and submitting a research proposal for funding, implementing the study, description and analysis of the research results, interpretation of the research results, and finally communicating the research, including its publication.

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World Medical Association, General Principles of Helsinki Declaration

- The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration".
- It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
- The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.
- Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
- It is the duty of physicians who are involved in medical research to protect the life, health,

dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

- Physicians must consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
- Medical research should be conducted in a manner that minimizes possible harm to the environment.
- Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional.
- Physicians who combine medical research with medical care should involve their patients in research only to the extent that

this is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

- Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.
- Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.
- Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.
- When the risks are found to outweigh the potential benefits or when there is conclusive proof of definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.
- The design and performance of each research study involving human subjects

must be clearly described and justified in a research protocol.

- Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.
- In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.

▶THE PROCESS OF OBTAINING CONSENT

- Identify participant population

- Produce information sheet and consent document
- Obtain permission from ethics committee
- Present research information to participant and discuss its contents – indicating that withdrawal at any time is possible
- Answer participants questions
- Give a copy of the consent document
- Allow the participant time to consider
- Meet participant and discuss documents, to

answer any more questions and assess participants understanding

- Obtain appropriate signed consent
- Start research

▶ANIMAL SUBJECTS

▶Should animals be used as research subjects?

- ▶ ABSOLUTELY NO ANIMAL RESEARCH - WHY?
- **Animals have rights!**

- Animals surely deserve to live their lives free from suffering and exploitation.

- Animals are not ours to:
  - eat
  - wear
  - experiment on
  - use for entertainment
  - abuse

▶Alright so, we know opinions differ

Yes

No

▶But, this is an ongoing debate that we're not here to engage!

▶ **WHEN CAN ANIMALS BE USED?**

- When there are no other alternatives.
- When confirmation has been made that research activities are not unnecessarily duplicating previously conducted experiments.
- Experiments involving animals are relevant to human or animal health, will advance scientific knowledge, or will be for the good of society.

▶ANIMAL RESEARCH ETHICAL CONSIDERATIONS

- When animals are used for research a scientist must avoid or minimize discomfort, distress, and painful situations.
- If a procedure involves more than momentary or slight pain or distress, it must be performed using appropriate pain relieving drugs (e.g. sedatives, analgesia or anesthesia).
- If animals are to be transported, appropriate arrangements must be made to ensure the process is comfortable and occurs with as little stress as possible.
- The living conditions of animals must be clean and appropriate for the species.