

RESEARCH ETHICS



مدينة الملك عبدالله الطبية
King Abdullah Medical City

Dr. Manal Z. Alfahmi

MBBS, SB-FM, AB-FM, JB-FM, MSc. Of Bioethics

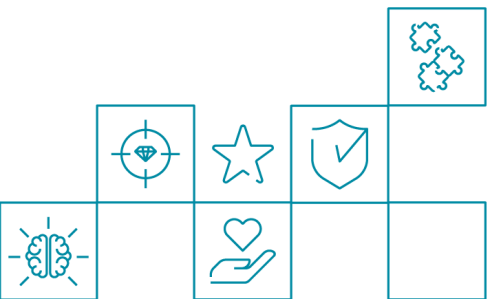
Consultant of Family Medicine & Bioethics

Director of Clinical Research Administration

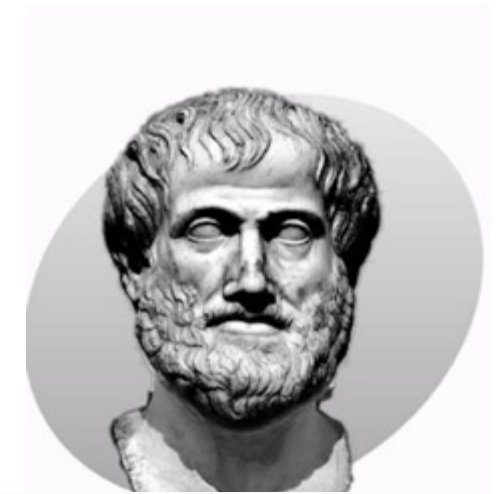
Chairperson of the Ethics Committee

➤ Objectives

- To promote ethically sound human research.
- To clarify the responsibilities of researchers for the ethical design, conduct, and dissemination of results of human research.
- To clarify the responsibilities of review bodies in the ethical review of research.



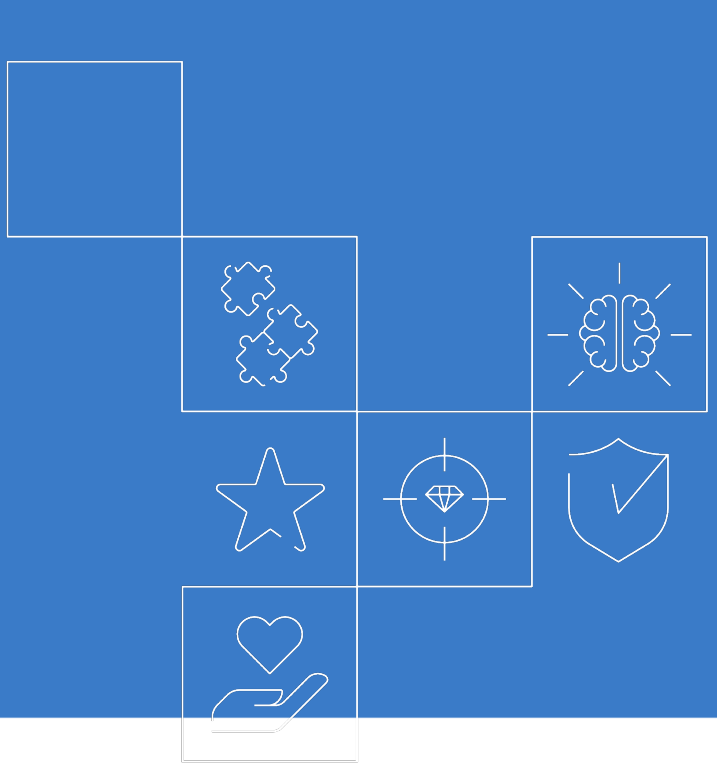
ETHIKOS



~ Aristotle ~





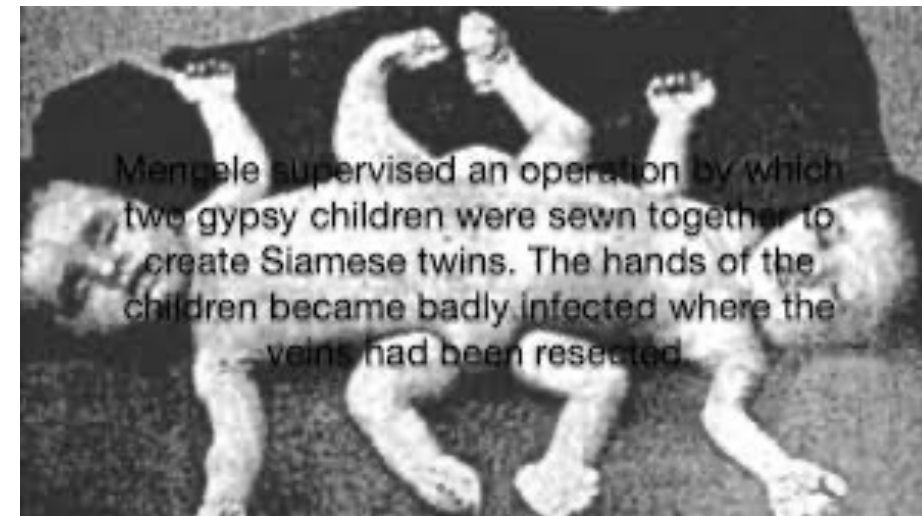


RESEARCH

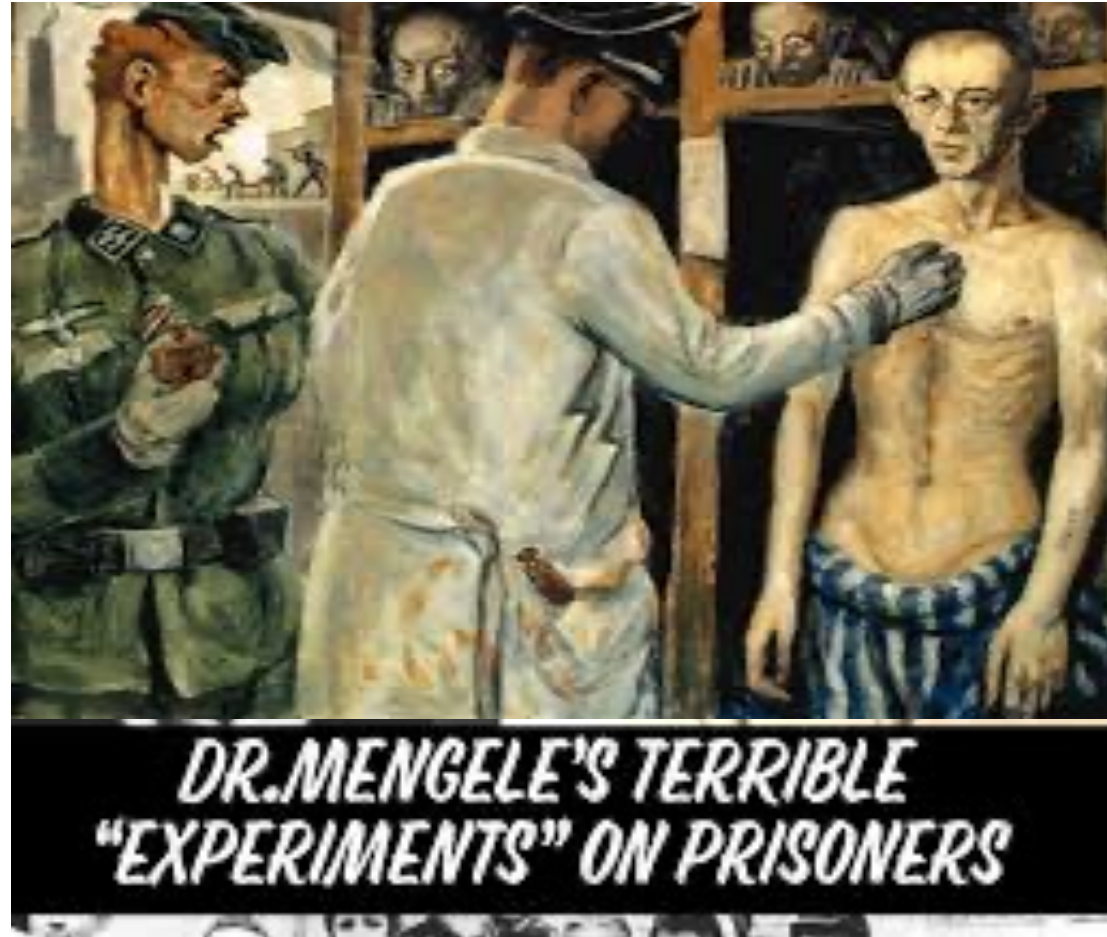


**Any activity designed to
test a hypothesis, develop
therapy, permit
conclusions & contribute to
generalizable knowledge.**

➤ Dr. Mengele's Experiments on Twin Children

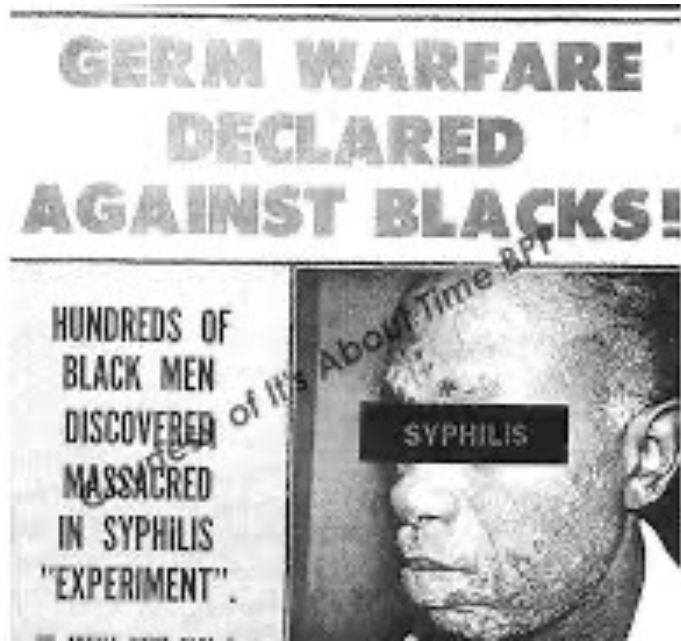


➤ Dr. Mengele's Experiments on prisoners



RESEARCH

➤ Tuskegee Syphilis Experiment



RESEARCH



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were

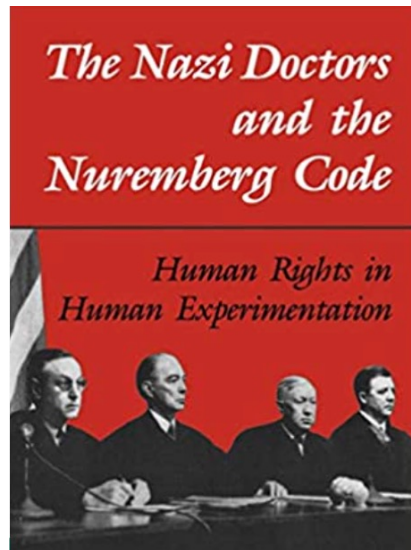
have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.





Nuremberg

City in Germany



1. Voluntary informed consent.
2. Fruitful result for the good of society.
3. Prior experimentation on animals, and prior knowledge of the problem.
4. Avoidance of unnecessary physical or mental injury.
5. Banning of known lethal or disabling procedures.
6. Degree of risks should not exceed benefits.
7. Proper preparation and facilities to prevent injury or death.
8. Performance of experiments only by scientifically qualified people.
9. Participants may freely end the experiment.
10. The experiment must stop if it proves too dangerous.



Declaration of Geneva

Adopted by the 2nd General Assembly of the World Medical Association, Geneva, Switzerland, September 1948
and amended by the 22nd World Medical Assembly, Sydney, Australia, August 1968
and the 35th World Medical Assembly, Venice, Italy, October 1983
and the 46th WMA General Assembly, Stockholm, Sweden, September 1994
and editorially revised at the 170th Council Session, Divonne-les-Bains, France, May 2005
and the 173rd Council Session, Divonne-les-Bains, France, May 2006

At the time of being admitted as a member of the medical profession:

I solemnly pledge to consecrate my life to the service of humanity;

I will give to my teachers the respect and gratitude that is their due;

I will practise my profession with conscience and dignity;

The health of my patient will be my first consideration;

I will respect the secrets that are confided in me, even after the patient has died;

I will maintain, by all the means in my power, the honour and the noble traditions of the medical profession;

My colleagues will be my sisters and brothers;

I will not permit considerations of age, disease or disability, creed, ethnic origin, gender, nationality, political affiliation, race, sexual orientation, social standing or any other factor to intervene between my duty and my patient;

I will maintain the utmost respect for human life;

I will not use my medical knowledge to violate human rights and civil liberties, even under threat;

I make these promises solemnly, freely and upon my honour.



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WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects ,1964

(amended a number of times since the original adoption)
(1975, 1983, 1989, 1996, 2000, 2002, 2004, 2008, 2013)

Nuremberg code 1947

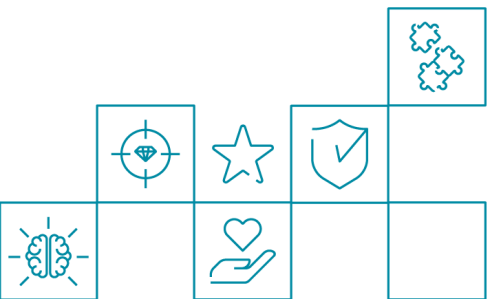


The **physician's knowledge** is dedicated to the fulfillment of their duty to **Safeguard the well-being** of patients involved in medical research



Generating new knowledge from research can never take precedence over the **rights and interests of research participants**

Medical research is subject to **ethical standards** that ensure **respect for human participants' rights to self-determination** and **protect their health**



➤ National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, 1979

Ethical Principles of the Belmont Report



➤ Guiding principles and their applications
for the ethical conduct of research

Respect for persons

Beneficence

Justice

Informed consent

Risk & Benefit

**Fair Selection of
participants**

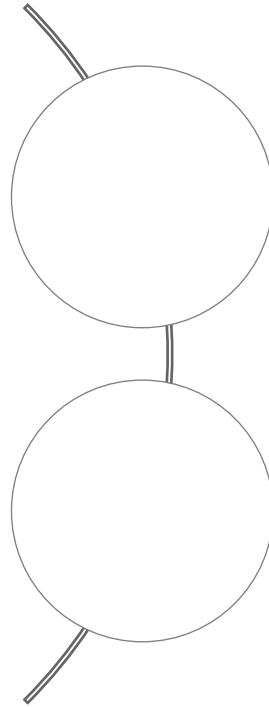
➤ Ethical Issue:

- Dr. X is offered a financial reward if he provides the names of patients to a third party who is coordinating a research study. Fees are based on the number of names provided!

Ethics
IRB
Human Subjects
Monitoring
Compliance Justice
Beneficence Respect
Education
Research



➤ Respect for persons



Every precaution must be taken to **protect the privacy of participants and the confidentiality of their personal information.**

No individual capable of giving informed consent may be enrolled unless **he or she freely agrees, participation Voluntary**



➤ Essential points of informed consent:

The aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher
– The option of being informed about the general outcome and results of the study

**Purpose
of the
research**

**Description
of what the
participants
will be
expected to do**

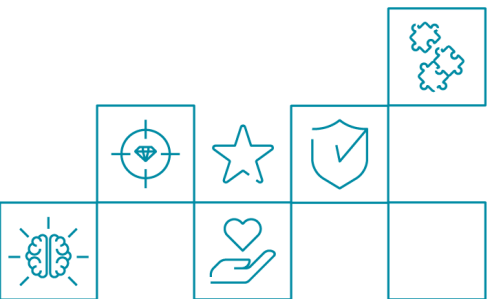
Fully inform which aspects of their care are related to the research – a qualified individual who is completely independent of the relationship

The anticipated benefits, potential risks, discomfort, post-study provisions & any other relevant aspects of the study

**Any
foreseeable
risks of harm**

**Participation is
voluntary and
are free to
withdraw at
anytime**

Refusal to participate in a study or the decision to withdraw from the study must never adversely affect the patient- physician relationship



➤ Beneficence

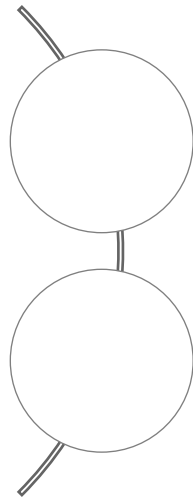
- To act for participants' benefits
- Refrain from harming participants
- Maximize benefits & Minimize harms



A favorable balance between the potential benefits and harms of participation



➤ Justice



Equitable distribution of the burdens and benefits of research

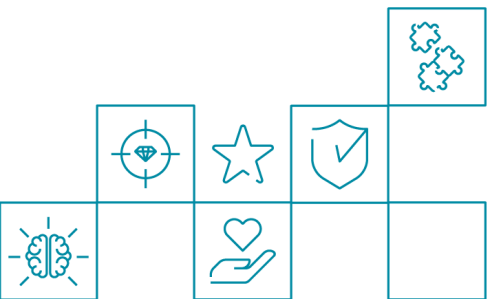
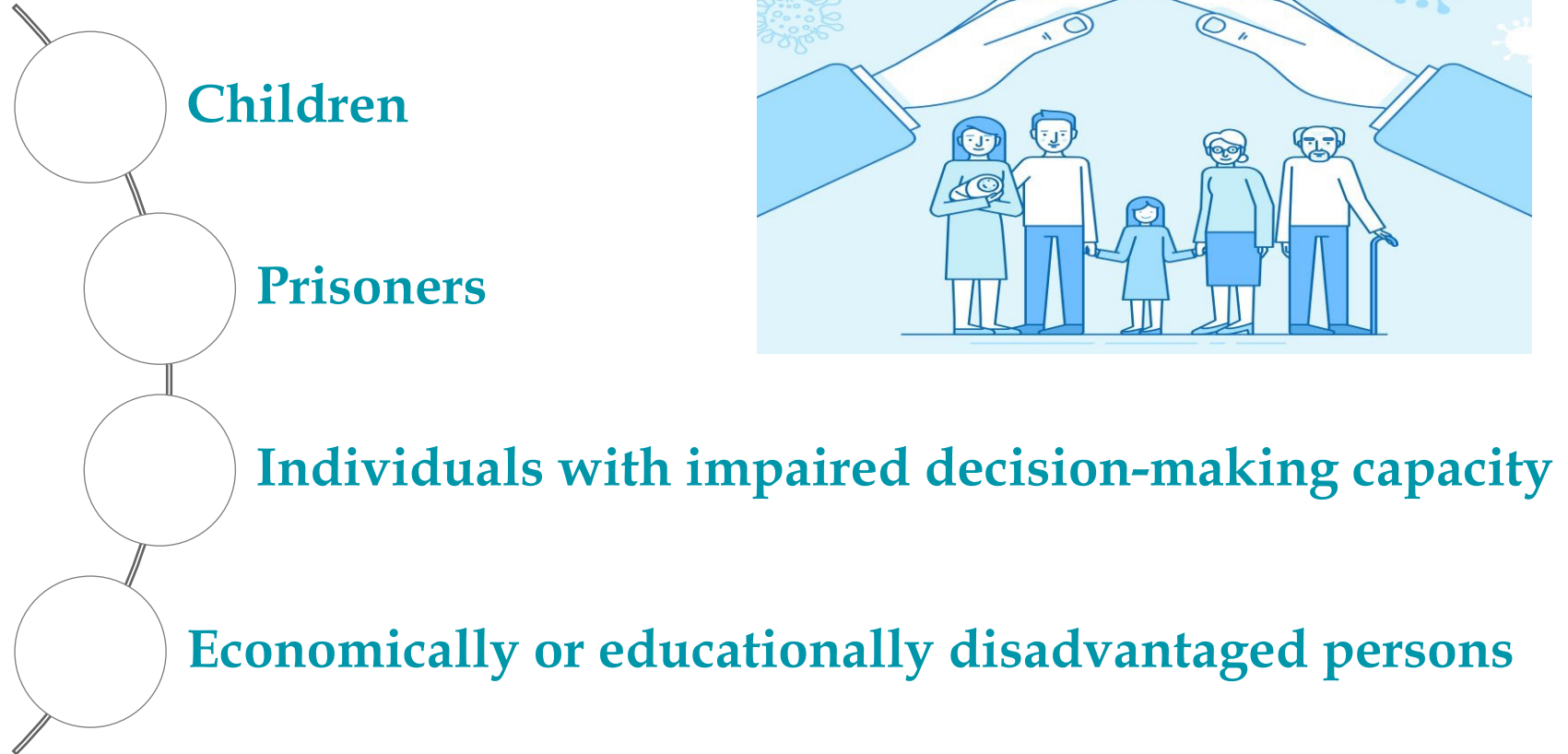
Eligible candidates who may benefit from participation not be excluded without good cause



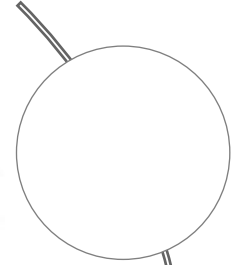
Fair selection of participants



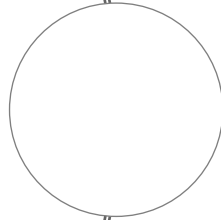
➤ Vulnerable populations:



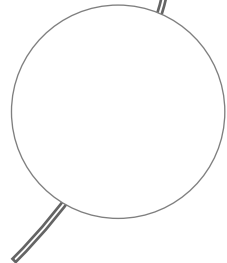
➤ Vulnerable Groups and Individuals:



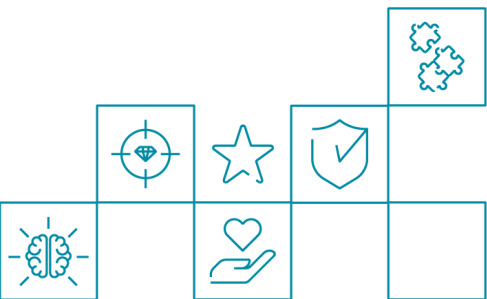
All vulnerable individuals should receive **specifically considered protection**

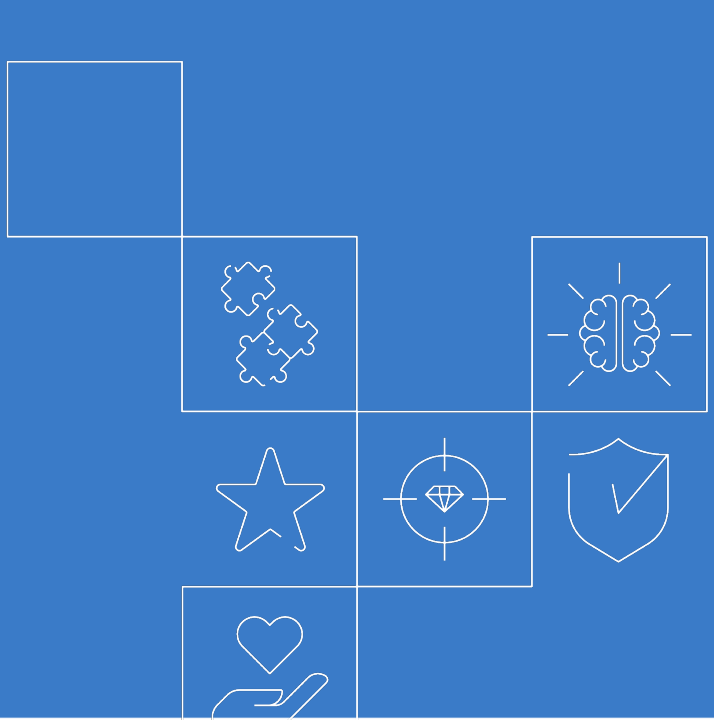


Only justified if the research is **responsive to the health needs or priorities of this group** and the research cannot be carried out in a non-vulnerable group

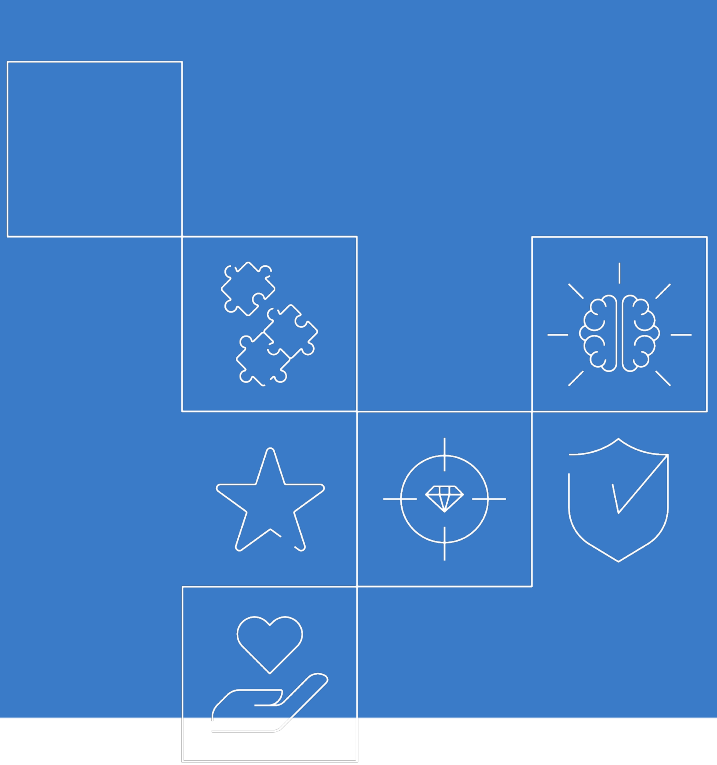


Stand to **benefit from the knowledge, practices, or interventions** that result from the research





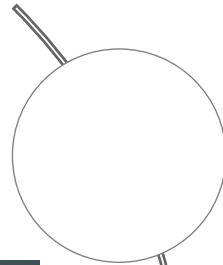
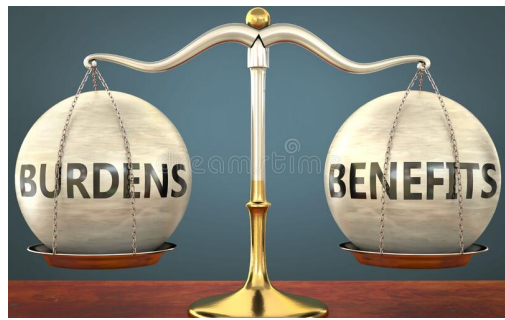
- **Are there limits to the obligation to run risks or do without benefits for the sake of research? If the only beneficiaries are people in rich countries, and those who will not benefit are the poor?**



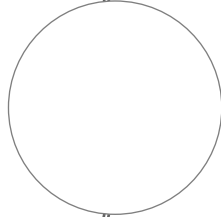
- **Research not allowed within the high-income countries' borders is carried out in other low-income countries.**
- **Areas of research not of interest to the host (low-income countries) health needs of a population!**



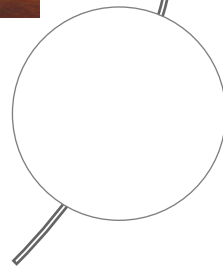
➤ Risks, Burdens, and Benefits:



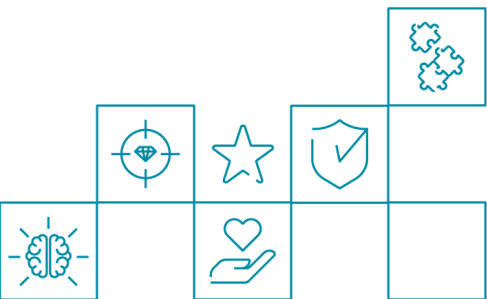
The importance of the **objective outweighs the risks and burdens** to the research participants



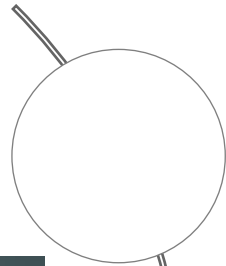
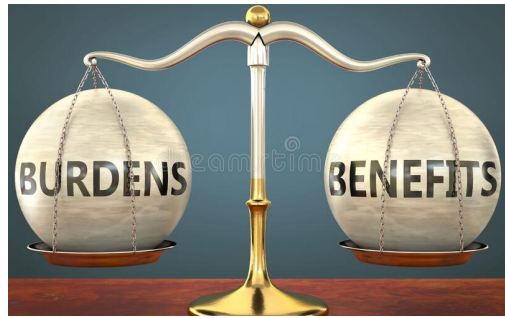
Careful assessment of **predictable risks and burdens to the individuals** involved in the research



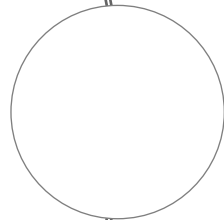
The risks must be **continuously monitored, assessed, and documented** and can be managed (**continue, modify or immediately stop the study**)



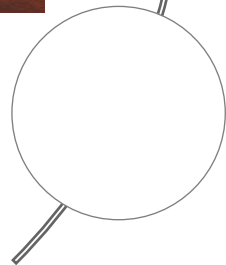
➤ Risks, Burdens, and Benefits:



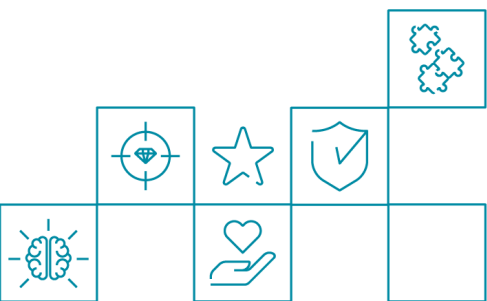
Groups that are underrepresented in medical research should be provided appropriate access to participation in research

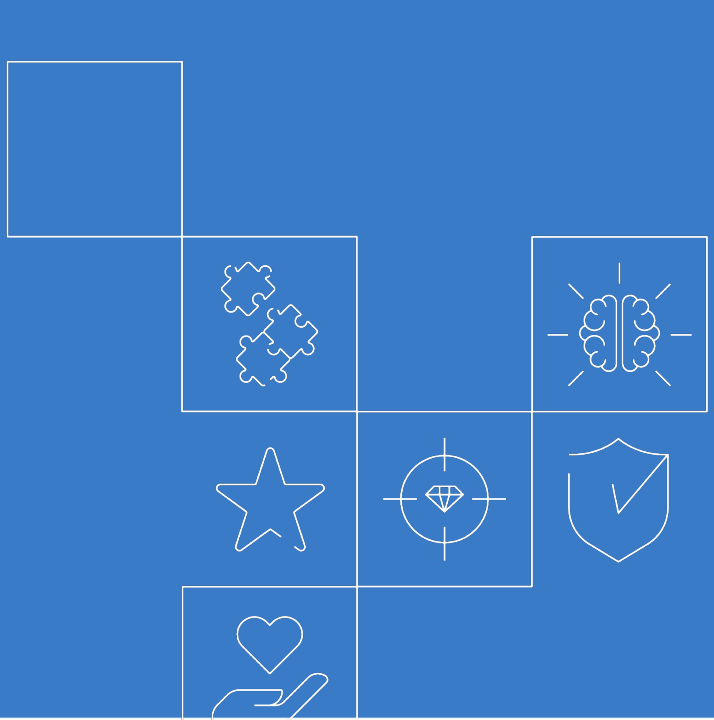


Potential preventive, diagnostic or therapeutic value and will not adversely affect the health of the research participants



Appropriate compensation and treatment for participants who are harmed as a result of participating in research must be ensured





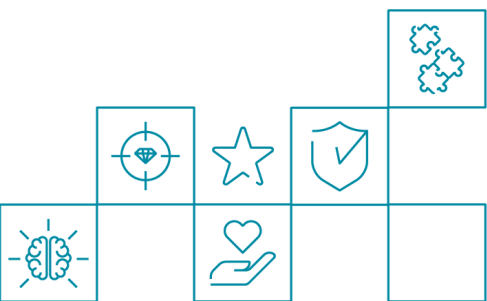
- **In a RCT, Is it ethically justifiable for some research participants to receive less than the ordinary standard of care (the known effective treatment)?**



➤ Criteria for identifying the standard of care is it:

- The **best available** treatment!
- The **most commonly** used treatment!
- The treatment **promoted** by the relevant authorities!
- The treatment **recommended** by the common textbooks!

STANDARD
OF CARE



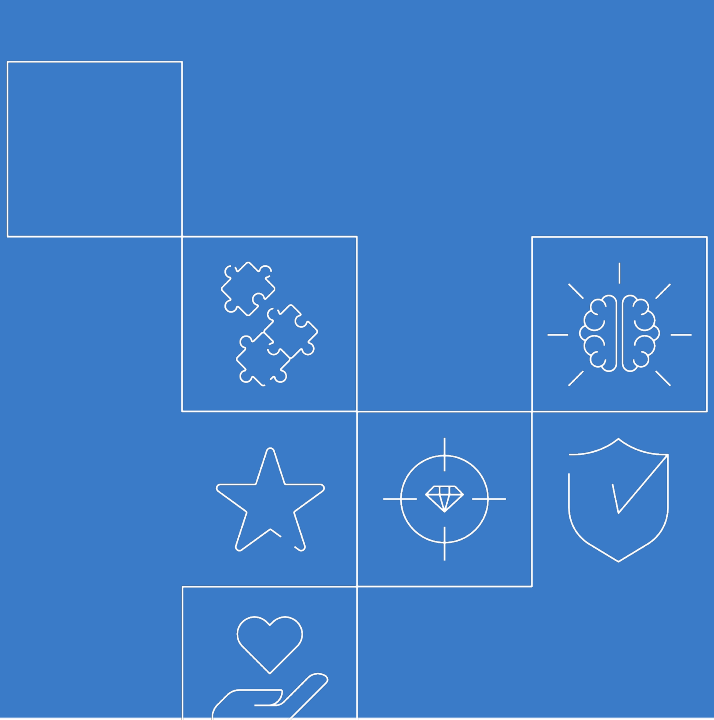
➤ Standard of care can be:

○ Changeable with time

○ Vary between countries and with in one country

○ The available **economic Resources** to the Health care (affordable)





- **Dr. Y is invited to enroll his patients in a placebo-controlled study of a new antipsychotic drug. Is it ethical for him to recommend the study to his patients?**



Ethical Issue:

Trials with Shorter versions of the regimen were initiated to develop affordable alternatives to other countries except for one study in Thailand that used a placebo in the control group. This led to a large debate!!!

AIDS clinical trials



The Council for International Organizations of Medical Sciences guidelines

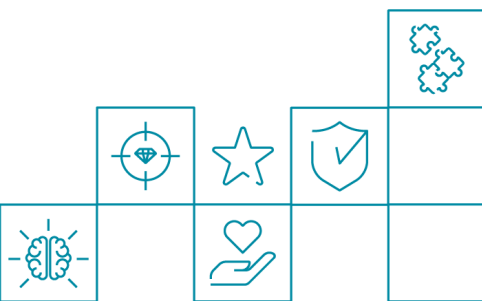


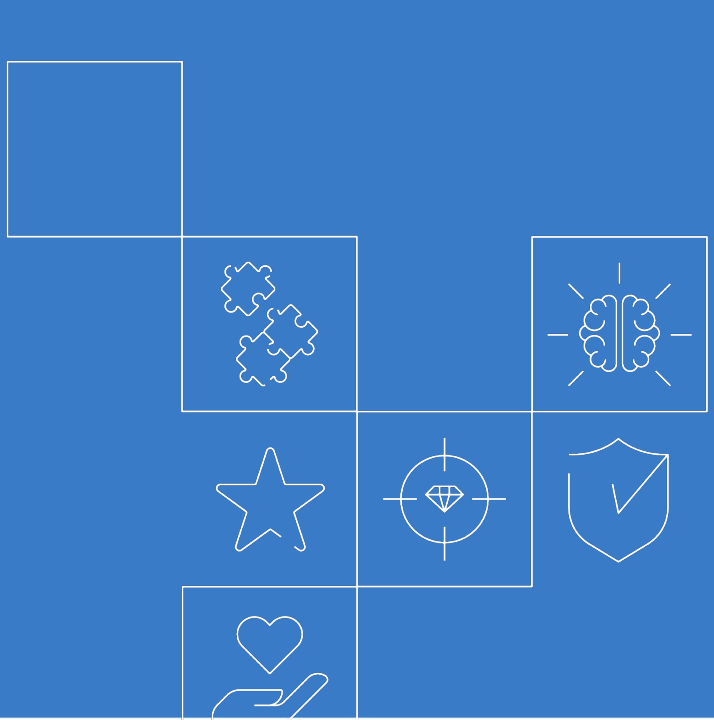
The CIOMS guidelines
2002, Placebo may be used:

No established
effective intervention

When Withholding an
established effective
intervention would
expose subjects to, at
most, temporary
discomfort or delay in
relief of symptoms

When use of an established
effective intervention as
comparator would not yield
scientifically reliable results
and use of placebo would not
add any risk of serious or
irreversible harm to the
subjects





➤ Ethical Issue:

- Is it ethically justifiable that by signing the trial informed consent, the research participants have accepted a particular standard of care?

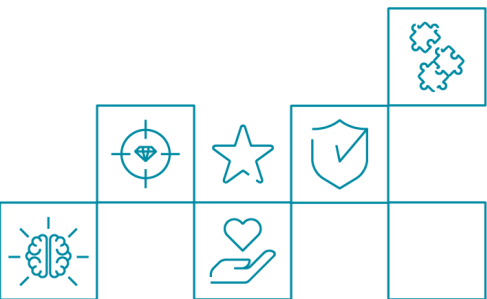




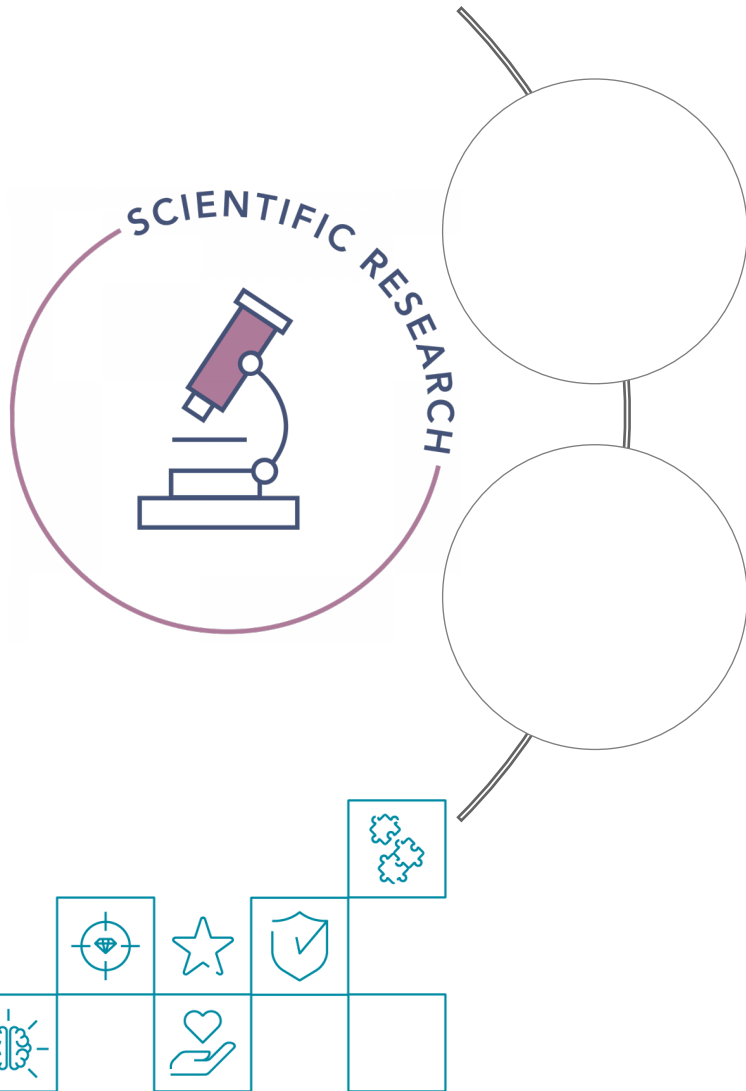
The core ethical rationale for maintaining a standard of care restriction in the planning of the research project

Research participation should not cause predictable harm by deprivation of known effective treatment

Against the researchers' professional obligations as health care professionals to treat any of their patients in a way that is not in the patients' best interest



➤ Scientific Requirements:



Medical research involving human subjects **must be conducted only by individuals with the appropriate ethics and scientific education, training**

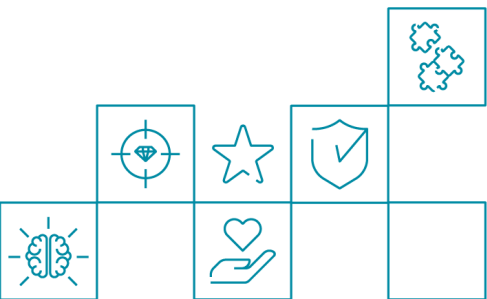
Research on patients or healthy volunteers requires **the supervision of a competent and appropriately qualified physician or other healthcare professional**

➤ Scientific Requirements:



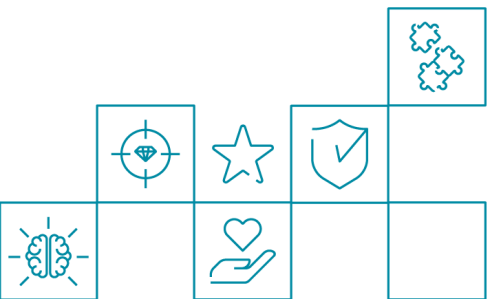
The ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards

Based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation



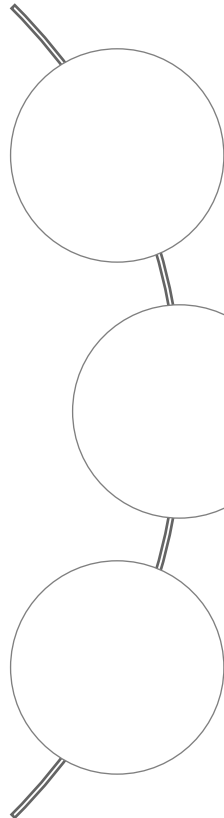
➤ The protocol should include information regarding:

- Funding, sponsors, incentives
- Institutional affiliations
- Potential conflicts of interest
- Provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study



➤ Research Ethics Committees:

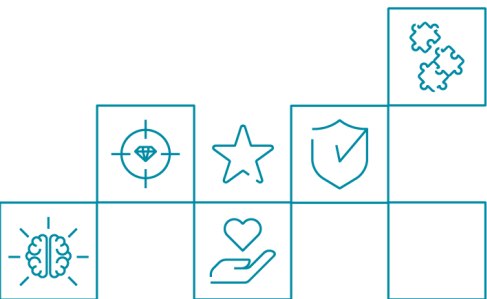
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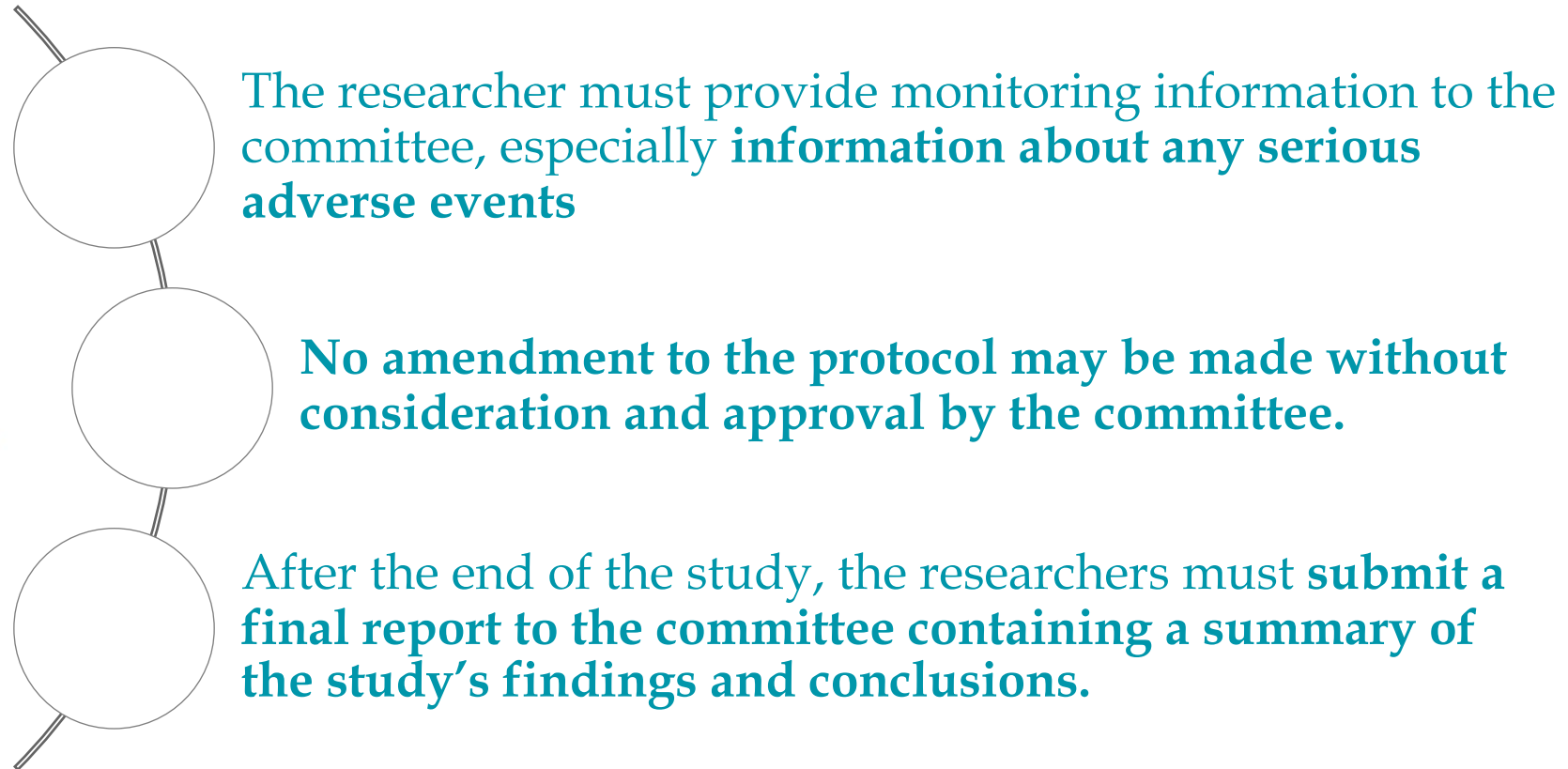
The research protocol must be submitted for consideration, comment, guidance, and approval to the committee **before the study begins**

Independent of the researcher, the sponsor, and any other **undue influence must be duly qualified**

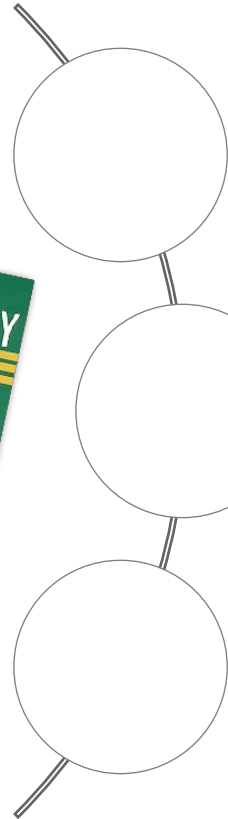
The laws and regulations of the country or countries in which the research is to be performed as well as **applicable international norms and standards**



➤ Research Ethics Committees:



➤ Research Registration, Publication & Dissemination of Results:



Ensure the completeness and accuracy of their reports, **study findings reported accurately and promptly**

Negative and inconclusive as well as positive results must be published otherwise made publicly available

Sources of funding, institutional affiliations and conflicts of interest must be declared in the publication







WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964
and amended by the:

29th WMA General Assembly, Tokyo, Japan, October 1975

35th WMA General Assembly, Venice, Italy, October 1983

41st WMA General Assembly, Hong Kong, September 1989

48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996

52nd WMA General Assembly, Edinburgh, Scotland, October 2000

53rd WMA General Assembly, Washington DC, USA, October 2002 (Note of Clarification added)

55th WMA General Assembly, Tokyo, Japan, October 2004 (Note of Clarification added)

59th WMA General Assembly, Seoul, Republic of Korea, October 2008

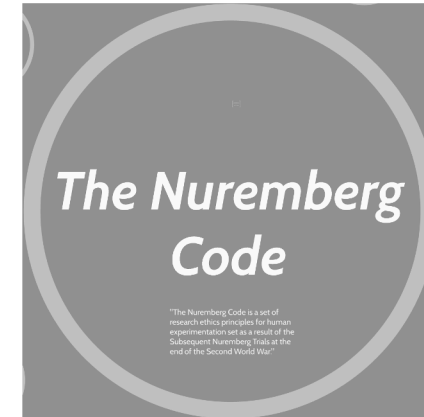
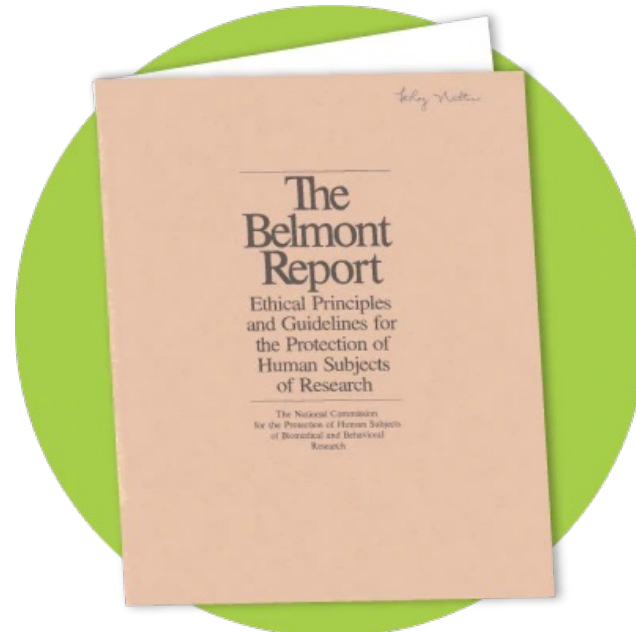
64th WMA General Assembly, Fortaleza, Brazil, October 2013



National Committee of BioEthics Implementing Regulations of the Law of Ethics of Research on Living Creatures

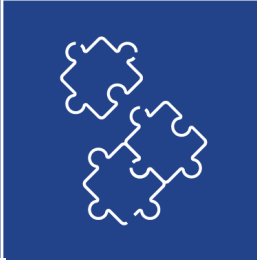
Version 3
2022

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King Abdullah Medical City



شكراً لكم
Thank You

