

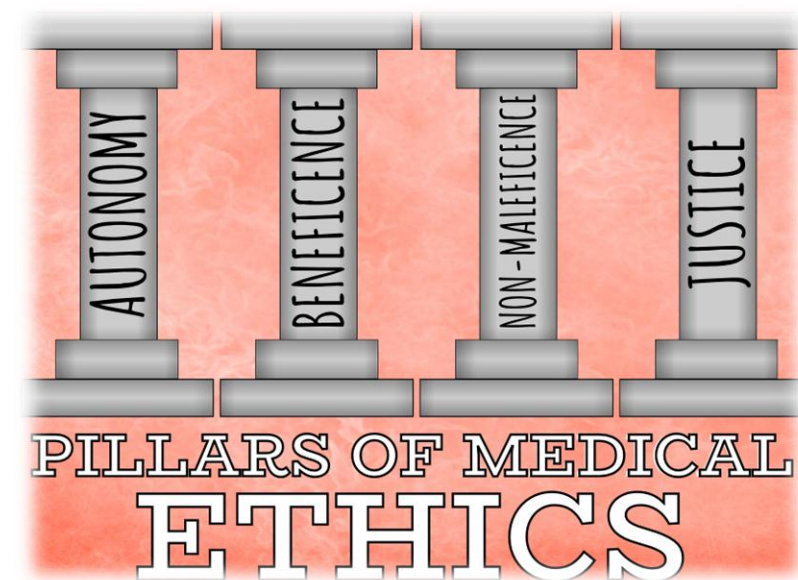
Health Research Ethics Committee

(*Helsinki Committee*)

Palestine

أخلاقيات البحث الصحي

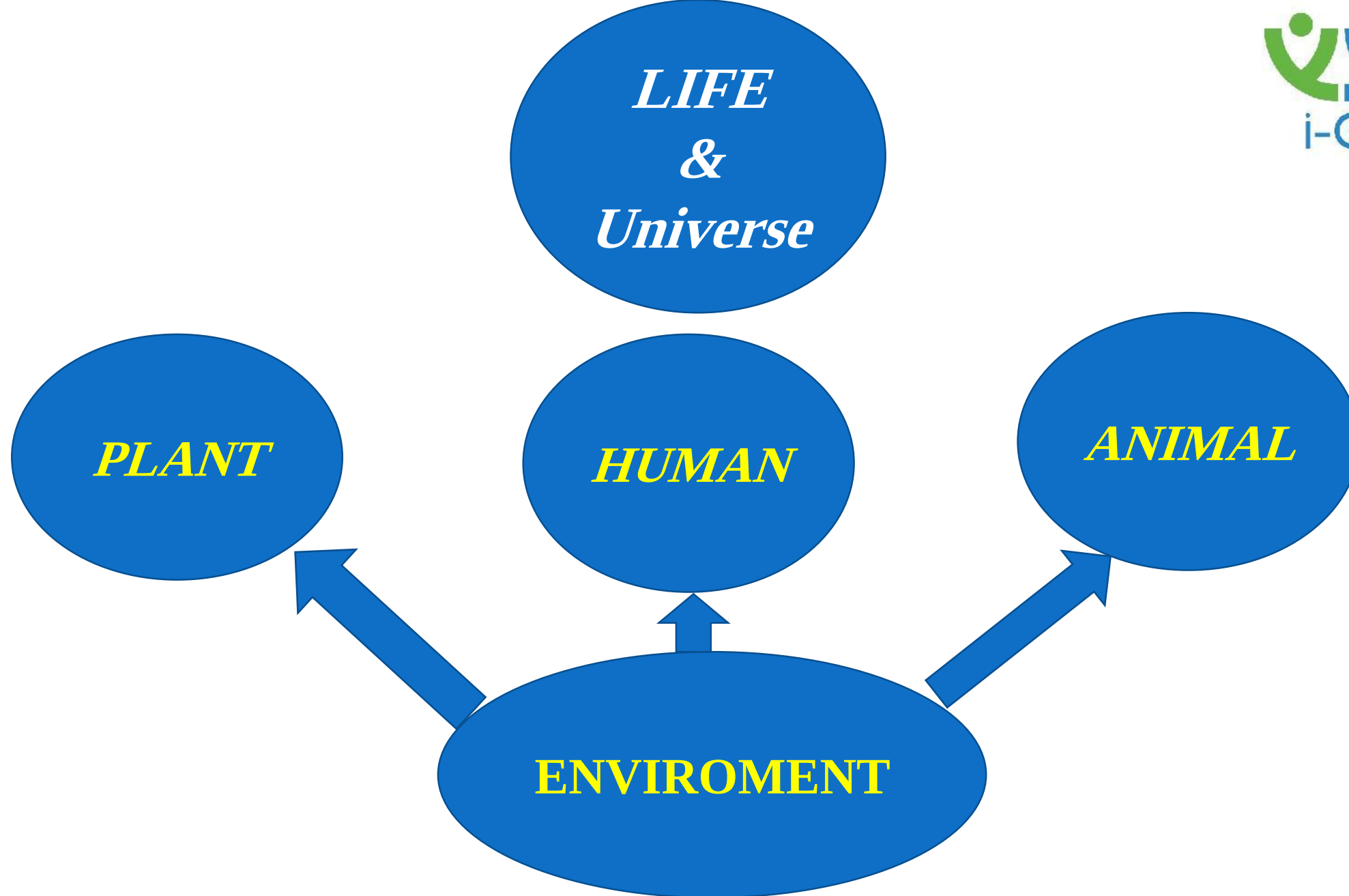
Bioethics



Dr. Assad M.H. Yousef

(خَلَقَ الْإِنْسَانَ * عَلَّمَهُ الْبَيَانَ)

[الرحمن: ٣ - ٤]

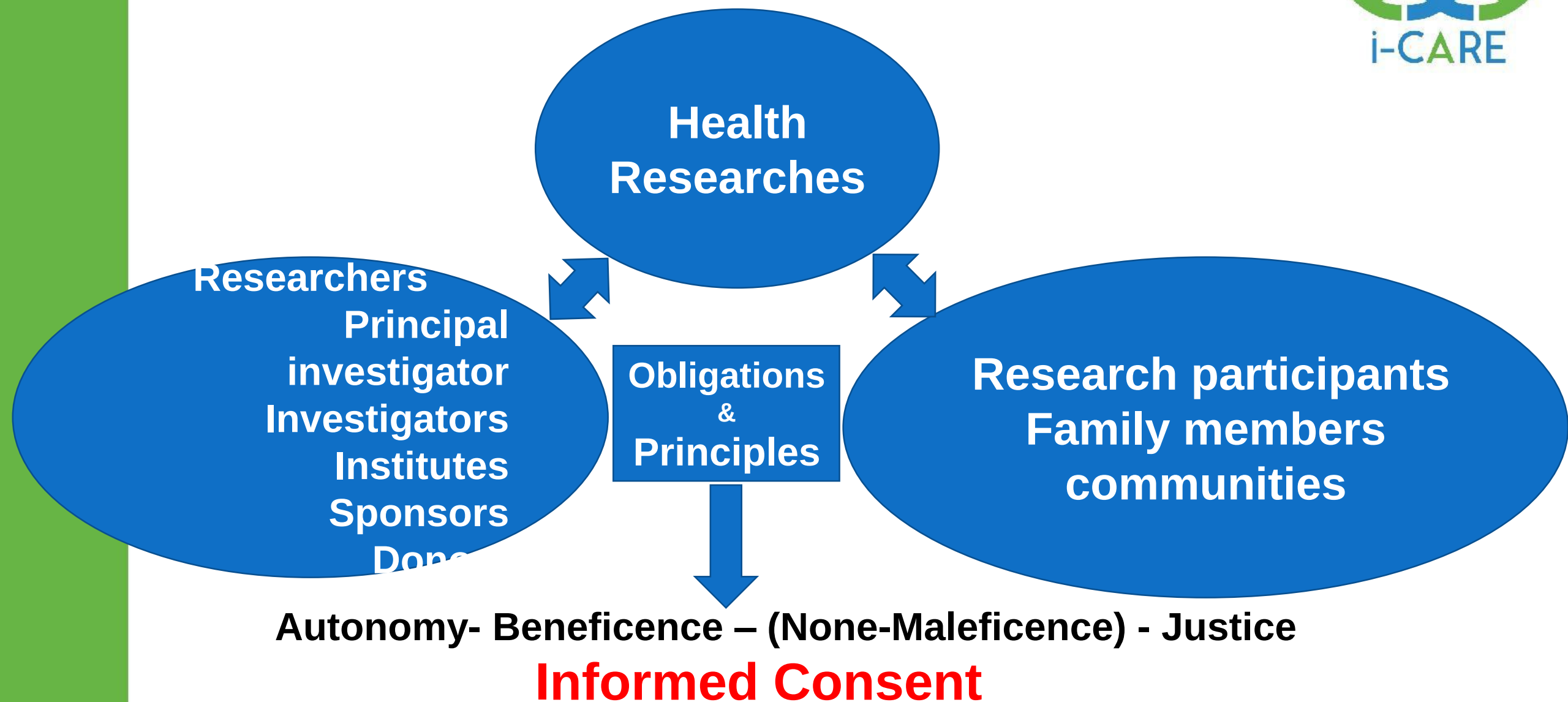


Health Definition

“A state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”

الصحة هي حالة من اكتمال السلامة بدنياً وعقلياً واجتماعياً، لا مجرد انعدام المرض أو العجز.

- مقتبس من ديباجة دستور منظمة الصحة العالمية، بصيغته التي اعتمدها مؤتمر الصحة الدولي المعقود في نيويورك في الفترة بين ١٩ حزيران/يونيو و ٢٢ تموز/يوليو ١٩٤٦؛ والتي وقّع عليها، في ٢٢ تموز/يوليو ١٩٤٦، ممثلو ٦١ دولة (السجلات الرسمية لمنظمة الصحة العالمية، المجلد ٢، الصفحة ١٠٠) ودخلت حيز النفاذ في ٧ نيسان/أبريل ١٩٤٨، ولم يخضع ذلك التعريف لأي تعديل منذ عام ١٩٤٨.



What is Research



"Any creative systematic activity undertaken in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this knowledge to devise new applications."

Or

"A process of steps used to collect and analyze information to increase our understanding of a topic or issue". It consists of three steps: pose a question, collect data to answer the question, and present an answer to the question.

❖ البحث العلمي أو البحث أو التجربة

- هو أسلوب منظم في جمع المعلومات الموثوقة
- تدوين الملاحظات والتحليل الموضوعي لتلك المعلومات باتباع أساليب ومناهج علمية محددة بقصد التأكد من صحتها أو تعديلها أو إضافة الجديد لها.
- من ثم التوصل إلى بعض القوانين والنظريات والتنبؤ بحدوث مثل هذه الظواهر والتحكم في أسبابها.
- البحث العلمي في رأي خبير اليونسكو Degenson John هو "استقصاء منهجي في سبيل زيادة مجموع المعرفة".



Health Researches



- ❖ Biomedical research
- ❖ Public health research
- ❖ Health policy and systems research
- ❖ Environmental health research
- ❖ Social sciences and behavioral research
- ❖ Operational research
- ❖ Health research as part of general “science and technology” research



Biomedical research (or experimental medicine)



❑ Wide array of research:-

- Basic research (also called *bench science* or *bench research*), involving fundamental scientific principles.
- Preclinical .
- Clinical research:- which involves studies of people who may be subjects in clinical trials.
- Clinical trials



Public Health Researches



- Research (Quantitative , Qualitative)
- Service Evaluation (Service development & Quality improvement)
- Clinical Audit
- Surveillance
- Usual Practice (In Public Health)



Service Evaluation, Clinical Audit, Research

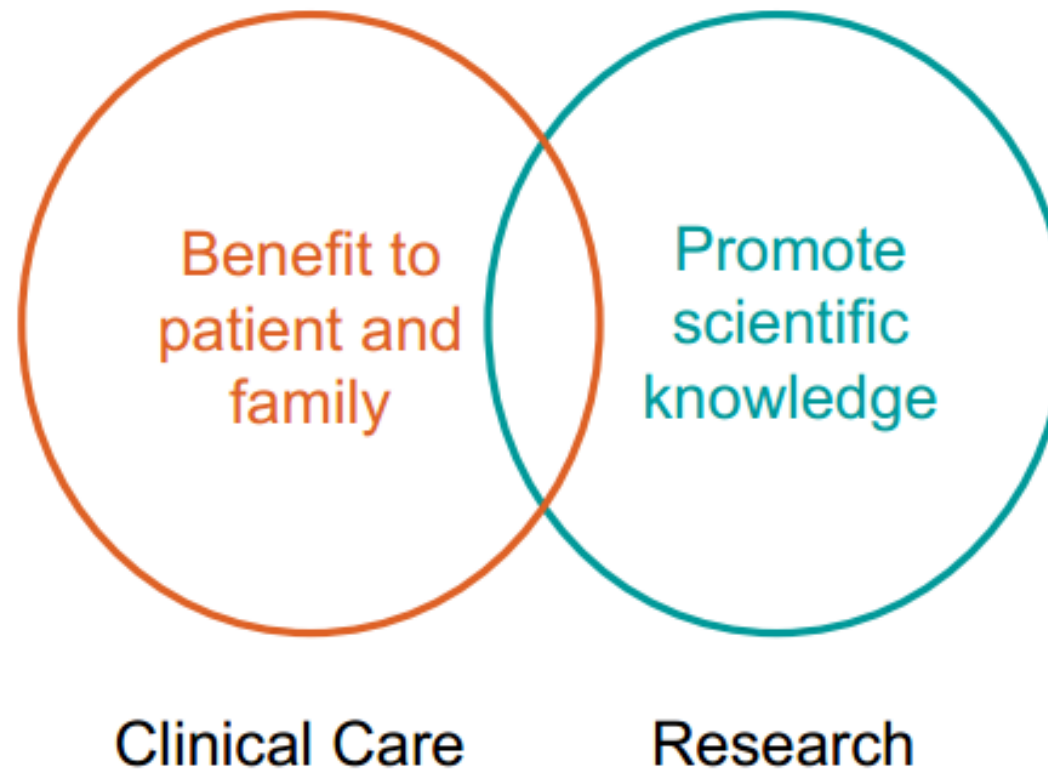


	Service Evaluation	Clinical Audit	Research
Overall aim (Intent)	To judge the quality of the current service	To measure clinical practice against a standard	To generate new knowledge/add to the body of knowledge
Initiated by	Service Providers	Service Providers	Researchers
Involves new TTT	NO	NO	Sometimes
Randomisation	NO	NO	Sometimes
Allocates patients to TTT groups	NO	NO	Sometimes

Goals



Goals are constrained by ethical obligations



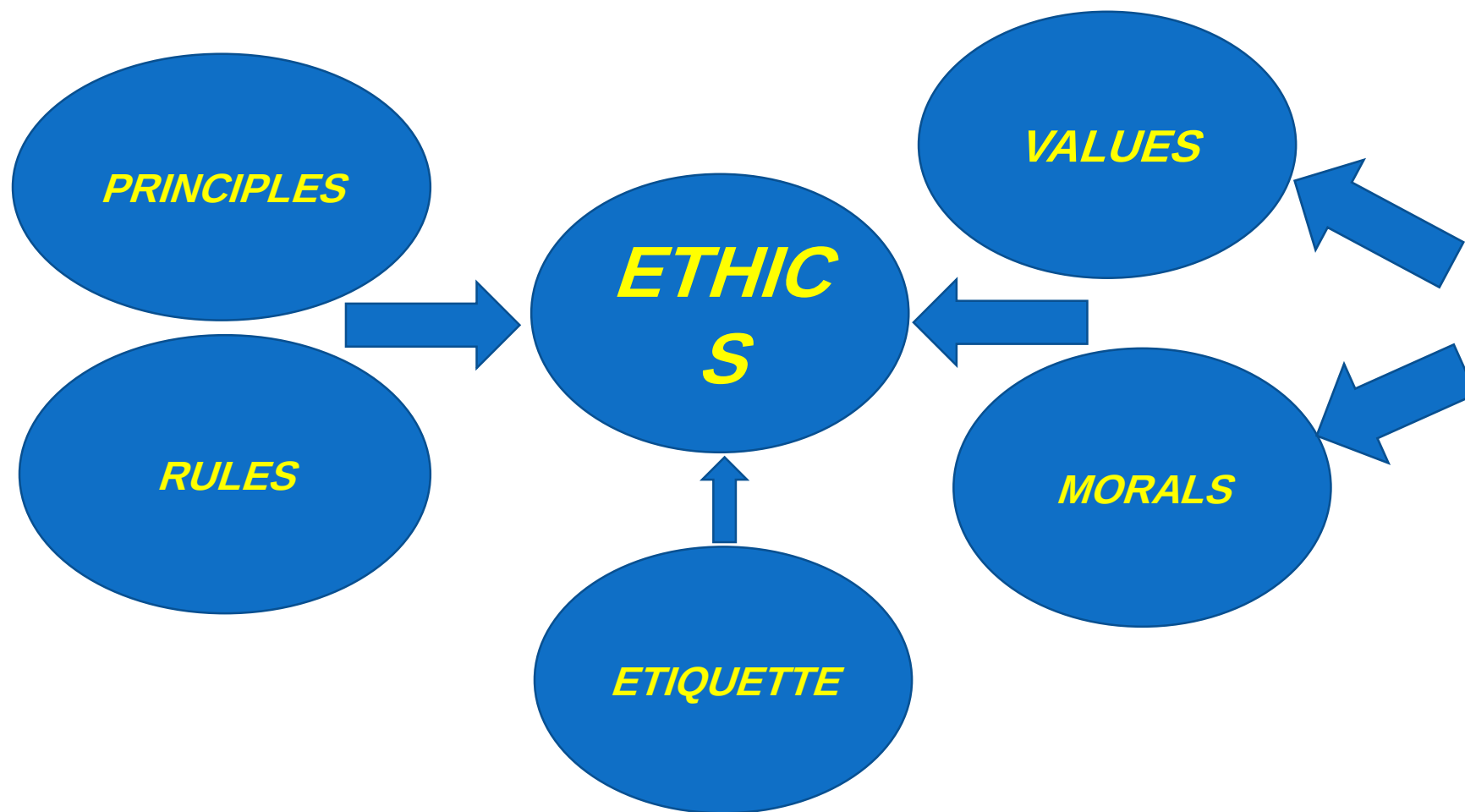
What is our mission?

Protect participants
and communities



Promote scientific
knowledge

ETHICS



RELIGIOUS

CULTURAL

SOCIAL

HISTORICAL

CONSTITUTIONAL

الأخلاقيات

- مجموعه من المبادئ والمعايير التي يقوم الإنسان بتطبيقها بشكل اختياري لاتخاذ قراراته حول مايقوم به من أفعال, وهذه المبادئ هي التي تحدد مدى صحة الفعل الإنساني

- الأخلاقيات هي مسأله فرديه تتعلق بالضمير



Ethics: A group of moral principles or set of values that define or direct us to the right choice

Islamic Ethics

- ❖ Refers to Islamic guidance on ethical or moral issues relating to medical and scientific fields, in particular, those dealing with human life.
- ❖ In Islam, human life is regarded as an *invaluable gift from ALLAH*, and should therefore be both respected and protected. This is evident in many *Qur'anic* verses or *ayat*.
- ❖ Specific issues addressed in the modern scientific era include abortion, fertility treatments, family planning, euthanasia, genetic research, cloning, stem cell research among many other issues

Bioethics

- ❖ *The systematic study of the moral dimensions - including moral vision, decisions, conduct, and policies- of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting.*

العلوم البيولوجية

❖ أن الإنجازات التي حدثت في العلوم البيولوجية (**Biological Sciences**) كانت الأهم على الإطلاق، خاصة ما يتعلق منها بالبحوث الصحية وروافدها الطبية.

❖ أهمية تلك البحوث لاتصالها المباشر بصحة الإنسان وحياته.

❖ دورها في إضاءة شعلة الأمل في قلوب ملايين البشر ممن يعانون من الأمراض المزمنة، أو التي لم يصل الطب إلى علاجها، بل تبشر تلك الأبحاث بتحول في الممارسات الطبية والعلاجية على نحو لم يدر في خلد أحد

Basic Documents for Health Research Ethics



- Nuremberg Code 1947
- Declaration of Geneva 1948
- Declaration of Helsinki 1964
- International covenant on civil & political rights 1966
- The Belmont report 1979
- International Ethical Guidelines for Biomedical Research Involving Human Subjects
- Council for International Organizations of Medical Sciences (CIOMS Guidelines) 1982
- International Conference on Harmonisation-GCP 1996
- The UNESCO Universal Declaration on Bioethics & Human rights 2005



الإعلان العالمي لحقوق الإنسان



" لا يجوز اخضاع أي انسان ----- الى معاملة أو عقاب قاس أو لا انساني أو مهين "

أن هذا الحظر يعني

" لا يجوز اخضاع أي شخص لتجارب طبية أو علمية بدون موافقته الحرة "

**No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment.
In particular, no one shall be subjected without his free consent to medical or scientific experimentation.**

International covenant on Civil and Political rights, Article 7, 1966



1947-The Nuremberg Code



- ❖ Developed in response to the Nuremberg trial of Nazi doctors who performed unethical experimentation during World War II, **the code was the first major international document to provide guidelines on research ethics.**
- ❖ It made **voluntary consent a requirement** in clinical research studies, emphasizing that consent can be voluntary only if:
 - Participants are able to consent
 - They are free from coercion (i.e., outside pressure)
 - They comprehend the risks and benefits involved.
- ❖ The code also states that researchers should **minimize risk and harm**, make sure that risks do not significantly outweigh potential benefits, use appropriate study designs and guarantee participant's freedom to withdraw at any time.



Photo of the Nuremberg
Palace of Justice



1964-Declaration of Helsinki



- ❖ World Medical Association in Helsinki, Finland **adopted 12 principles** to guide physicians **on ethical considerations** related to biomedical research.
- ❖ It emphasizes the **distinction between medical care** that directly benefits the patient **and research** that may or may not provide direct benefit.
- ❖ These guidelines were **revised** at subsequent meetings in 1975, 1983, 1989, 2000, 2008 and 2013.



1979-The Belmont Report



- The report sets forth **three principles** underlying the ethical conduct of research.
- ❖ **Respect for persons:** Recognizing the **autonomy and dignity** of individuals and the need to protect those with diminished autonomy (i.e., impaired decision-making skills), such as children, the aged and the disabled.
- ❖ **Beneficence:** An obligation to protect persons from harm by maximizing benefits and minimizing risks.
- ❖ **Justice:** Fair distribution of the benefits and burdens of research.
- The Belmont Report explains how these apply to research practices; for example, it identifies **informed consent** as a process that is essential to the principle of respect.



1982-CIOMS Guidelines



- ❖ In 1982, the WHO and CIOMS created **the International Ethical Guidelines for Research involving human subjects.**
- ❖ Most recently amended in 2002, the goal of the guidelines is to **support** and help **implement** the ethical principles of the **Helsinki Declaration** “particularly in developing countries, given their socio-economic circumstances, laws and regulations and executive and administrative arrangements.”
- ❖ The guidelines identify **26 separate items** of information an investigator must provide to trial participants prior to obtaining their **informed consent.**



-



The UNESCO Universal Declaration on Bioethics & Human rights

(Fifteen Bioethical Principles)



Human dignity & Human rights. •

Equality, justice and equity •

Benefit and Harm. •

Nondiscrimination & non stigmatization •

Autonomy & individual responsibility. •

Respect for cultural diversity & pluralism •

Consent. •

Solidarity & cooperation •

Persons without the capacity to consent. •

Social responsibility & health •

Respect for human vulnerability & personal integrity. •

Sharing of benefits •

Privacy & confidentiality. •

Protecting future generations •

Protection of the environment, the biosphere & biodiversity •



الاعتبارات الأخلاقية للبحث العلمي

Ethical Considerations for Scientific Research



Truthfulness
Expertise
Safety
Trust
Consent

Digital Recording
Feedback
False Hope
Vulnerability
Exploitation
Anonymity
Animal Rights



المصداقية
الخبرة
السلامة
الثقة
الموافقة
الانسحاب

Withdrawal

التسجيل الرقمي
التغذية الراجعة
الأميل المزيف / الكاذب
مراعاة مشاعر الآخرين
استغلال المواقف
سرية المعلومات
حقوق الحيوان

المبادئ الأخلاقية الأساسية للبحوث الصحية



Autonomy❖

❖ احترام الأشخاص والاستقلالية

Beneficence❖

❖ المنفعة

maleficence - Non❖

❖ عدم الضرر

Justice❖

❖ العدالة

Veracity❖

Fidelity❖



Autonomy

❖ „Self-Rule”

- Promotes participants to act as their own agent
- **Free will with Informed Consent**
- Respecting patient's choice

Beneficence

- ❖ **Do good** (or „provide benefit“)
- The basic principle of “caring”
- Act in accordance with a participant's welfare
- Doing what is in the best interests of your patient

Non - Maleficence

❖ **Do no harm**

- The calculation of risk in research decision.
- Making and determining risk/benefit ratio.
- The balance of benefit and harm = utility.

Justice

- ❖ **Be fair** (distributive justice > entitlement)
 - The appropriate distribution of limited resources.
 - Non discrimination
 - Transparency, accountability and consistency
 - Doing what's best for society as a whole

Truth-telling or Veracity:

❖ **Full, honest disclosure**

Fidelity:

- ❖ **Do as you say you will do**
- Respect confidentiality

Informed Consent



- ❖ *The process of obtaining a **patient's permission** for a procedure after the patient and doctor have discussed the risks, benefits, and alternatives of the procedure and the patient understands them.*
- ❖ *Informed Consent is a **voluntary agreement to participate in research**. It is not merely a form that is signed but is **a process**, in which the subject has an understanding of the research and its risks*



عناصر الموافقة المستنيرة



Disclosure❖
Understanding❖
Competent❖
Voluntariness❖
Agreement❖

❖ الإفصاح
❖ الفهم
❖ الأهلية
❖ الطوعية
❖ الموافقة



□ الإفصاح ← اخبار المشاركون بالمعلومات المتعلقة بالبحث.

□ الفهم ← وعي المشاركون وإدراكه لهذه المعلومات.

الإفصاح والفهم من المتطلبات الأساسية لصحة الموافقة فهما يحققان :-

أ/ المشاركة الفعالة والمستنيرة من قبل المشاركون في اتخاذ القرار المتعلق بالرعايته الصحية

ب/ إقامة علاقه يسودها الثقة بين الباحث والمشارك

□ **الاهلية** ← ان يكون المشارك مؤهل لفهم المعلومات المتعلقة بقرار معين وفهم عواقب ونتائج ذلك ، فمثلا قد يكون الفرد مؤهل لاتخاذ قرار يتعلق بمحل سكنه "لكنه غير مؤهل لاتخاذ قرار يتعلق بدواء معين او المشاركة في بحث طبي.

- فمبدأ عدم الحاق الاذى يتطلب من الباحث حماية المشاركين غير المؤهلين لاتخاذ القرار.

□ **الطوعية** ← حق المريض في اتخاذ القرار المتعلق بالعلاج او المشاركة في بحث طبي طوعية وبعيدا عن اي ضغوط خارجية ' والتي تتمثل في قدرة الآخرين علي فرض ارادتهم علي المريض بالاكراه، وتعد الطوعية مطلب اخلاقي لصحة القرار و ترتبط الطوعية بالعديد من المفاهيم الاخلاقية "الحرية، الاستقلالية، القدره علي اتخاذ القرار"

□ **الموافقة** ← " موافقة المريض علي المشاركة بناء علي ادراكه لاهمية دوره في البحث "

Informed Consent Form Elements



- Name of Institution
- Title of Project
- Principal Investigator
- Other Investigators
- Participant's Names
- Purpose of Research
- Procedures
- Time Duration of Procedures and Study
- Discomforts and Risks
- Potential Benefits
- Statement of Confidentiality
- Costs for Participation
- Compensation for Participation
- Research Funding
- Voluntary Participation
- Contact Information for Questions or Concerns



لجنة أخلاقيات البحث الصحي

فلسطين

(HREC- Helsinki)



- ❖ **1989** ----- Directorate of Health
- ❖ **1996** ----- Ministerial decree / Ministry of Health
- ❖ **2002** ----- Ministerial decree / Ministry of Health
- ❖ **2013** ----- Ministerial decree / Palestinian Health Research council





MISSION



- ❖ Ensure that researchers **adhere to the ethics of scientific research**, maintain the safety of researchers, participants in the research and the application of **safety standards**.
- ❖ **Oversight, follow-up** on research and develop a framework, rules for measuring the ethics of health research in all fields.





Vision



- ❖ **Research excellence and commitment to ethical principles** and achieve scientific innovation in the areas of health and community service while adhering to ethical principles.
- ❖ To envisage to the committee, **the continuation of the strategic plan to achieve better aspirations** in linking the principles of the ethics of scientific research with the reality of research.



Committee Tasks



- ❖ The **main task** of the committee is to **review health research projects** conducted in all health, academic and other institutions to verify the scientific and ethical integrity of such researches
- ❖ To **ensure protection** and **respect for human rights**, **environmental** protection, and **animal** protection
- ❖ **Prevention** of physical, moral and psychological **harm to research participants**
- ❖ Ensure **Equity, justice & truth** in **all activities** related to research work
- ❖ **Consider & evaluation** the research proposals from the **scientific and ethical dimensions** provided by the researchers, and make the appropriate decisions thereon
- ❖ **Issue** written **approvals (two years)** for research projects
- ❖ **Monitor the commitment** of researchers to comply with ethical standards and organize informed consent procedures
- ❖ **Transparency** in access to **financial support** for research





المجلس الفلسطيني للبحث الصحي Palestinian Health Research Council

تعزيز النظام الصحي الفلسطيني من خلال مؤسسة استخدام المعلومات الصحية في صنع القرار

"Developing the Palestinian health system through institutionalizing the use of information in decision making"

Helsinki Committee Request for Approval

A: Personal Data

Date:	
Name:	Residency:
Institution:	Specialty:
Degree:	Place of work:
Mobile:	Email:

B: Proposal Details

1. Title:

2. Objectives:

3. Methodology

3.1. Study design

3.2. Study population:

3.3. Expected date of data collection:

Check the second page to give details of data collection

E-Mail: pal.phrc@gmail.com

Gaza - Palestine

غزة - فلسطين



المجلس الفلسطيني للبحث الصحي Palestinian Health Research Council

تعزيز النظام الصحي الفلسطيني من خلال مؤسسة استخدام المعلومات الصحية في صنع القرار

"Developing the Palestinian health system through institutionalizing the use of information in decision making"

3.4. Data collection:

Questionnaire	Yes	No
Blood testing	Yes	No
If Yes: Who will draw the blood?		
Tests to be done		
Other tissues or specimen exams	Yes	No
If Yes: Specify		
Are you giving drugs?	Yes	No
If yes: Give details of the medication:		
Are you intending to perform surgical or physical procedures?	Yes	No
If yes: Describe:		
Do you plan to get informed consent	Yes	No
If No: Justify:		
If you have further details please add Here:		
All the given information are TRUE		Signature

E-Mail: pal.phrc@gmail.com

Gaza - Palestine

غزة - فلسطين

Ethical Approvals



According to area 2018	According to institute 2018	According to Year	From Abroad
Gaza Strip 130	Al Quds University faculty of public health Gaza 43	2015 and before 75	Norway 12
West Bank 8	MOH 38	2016 117	USA 2
Outside Palestine 34	Al Azhar University 33	2017 114	UK 3
Total 172	Islamic University 19	2018 172	Germany 1
	Others 39	2019 23 cont.	





Future Prospective



- ❖ To emphasize the **continuity** of the committee's work to evaluate research according to ethical standards in all its dimensions.
- ❖ Continuing **regularity** of the committee's working hours according to the internal regulatory rules.
- ❖ Permanent **revision of the rules of procedure** and members activity participation, in order to ensure the best performance.
- ❖ Continuous **communication with all partners** (scientific, educational, health, research and environmental health services) to demonstrate the utmost importance of the ethical principles of health research.
- ❖ Emphasis on activating the role of coordinators (**Liaison Officer**) in universities and related health and research institutions.
- ❖ Spreading **community awareness** about the importance of ethical research and the ***Importance of Informed Consent.***
- ❖ The possibility of **holding training courses** and rehabilitation in the principles of research ethics.
- ❖ The **active participation** of all spectra of **health researchers in** expressing positive opinions and suggestions.



Conclusion



- ❖ Health researches are **governed by ethical standards** based on respect for all human beings, protection of their rights and preservation in the best of health.
- ❖ It is the duty of researchers to **protect** life, health, human dignity, the right to express consent to participate in research freely, privacy, confidentiality of personal information.
- ❖ Medical / health research should be carried out with the **least harm** to humans and the environment, and those who carry out such research shall be experts with scientific and ethical expertise.
- ❖ **Finally**, the main goal of medical / health research in humans to **find a cure for diseases, improve diagnostic and preventive methods, and to be a slogan of safety, effectiveness, efficiency, equity and accessibility to every patient who needs them** "



No science without research ,, No research without Ethics

لا علم بدون أبحاث ولا أبحاث بدون أخلاق

إن المكارم أخلاق مطهرة الدين أولها والعقل ثانيها

والعلم ثالثها والحلم رابعها والجود خامسها والفضل سادها

والبر سابعها والصبر ثامنها والشكر تاسعها واللين باقيها

والنفس تعلم أني لا أصادقها ولست أرشد إلا حين أعصها

شعر علي بن أبي طالب
رضي الله عنه

Thank You



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