
MEDICAL RESEARCH
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Ethics in medical research: part 1 introduction

Color code

- Slides
- Doctor
- Additional info
- Important

- Ethics in medical research,These standards include protecting human subjects, ensuring the confidentiality and security of data, and, above all, avoiding any harm to participants—whether mental, physical, or social. No research project should proceed without ensuring that the core aim is to improve outcomes for participants while guaranteeing their safety and well-being.

- When conducting research, two essential aspects must be addressed:

1. Proposal Writing Methodology:

- A scientifically acceptable and valid methodology must be followed. For instance, when comparing two medications, such as Medication A and Medication B, the study design should involve a clinical trial—preferably a randomized controlled double-blind or triple-blind trial. This requires agreeing on the doses for each medication, defining inclusion and exclusion criteria, and identifying the primary and secondary outcomes of the study.

2. Ethical Considerations in Clinical Trials:

- It is vital to ensure that the trial does not harm patients and demonstrates a potential benefit for individuals with the targeted illness.Participation must be voluntary, with participants having the right to join or withdraw at any stage without any negative impact on the medical services provided to them. For example, if a participant withdraws after three months of a four-month follow-up trial, their decision must not affect the quality of clinical care they receive during or after the study.Participants must be fully informed about the trial, including its potential risks and benefits.

- Ethical Approval Process:

- Before initiating any medical research project, ethical approval from the Institutional Review Board (IRB) is mandatory. This applies to all studies, from clinical trials to simpler research activities like surveys. Depending on the study, there are two types of approvals:

- Expedited Approval: This applies to studies that pose minimal risk, such as surveys that do not collect sensitive data or identifiable information, or those that avoid invasive procedures (e.g., blood sampling).

- Full Review: Studies involving blood collection, medical note reviews, cohort follow-ups, or clinical trials require a thorough review, as they may pose greater risks.

- Researchers cannot decide the type of review their study requires; this is determined by the IRB. Starting a study without IRB approval is illegal, unethical, and violates the law. As students or future medical professionals, it is critical to recognize that adhering to these processes is not optional.

Research

- Research is the systematic collection, analysis and interpretation of data to answer a certain question or solve a problem

How to Minimize Risks to Research Participants:

- Studies that require IRB approval:

a. Data from living individuals

b. Biological material from living individuals

c. Interaction or intervention with a living individual

d. Use of a non-approved, drug, device or biological

Examples
Sometimes we want to give a terminal ill patient certain situation something to risk their lives and the medication still not approved we need to apply for IRB approvals for to get approval for the

use of non-approved drug or device or biological but this point D varies between countries some count require IRB approval some requirements they will they need an expedited approval from the Food and Drug Administration Department in that country so Point D varies between countries

Clinical Trials Phases (0-IV)

We should not Conduct any of these 5 phases without IRB approval.

- Each of these types of study requires the appropriate design to reach scientifically sound conclusions while protecting the participants and their identifiable human information.

Ethical Design In Clinical Research

Although this may be morally obvious, it's also important practically because of the huge investments in money, effort, and personal risk and discomfort that the sponsor, investigators and the participants make.

So we need to avoid start any such research projects without having the ethical approval ,our proposal should be ethically acceptable as well

Ethical Design In Clinical Research

- Poorly designed and executed studies are frequently reported and can even influence practice and policy development.

- Among elements that make for poor and therefore unethical science are:

1. Excessive risks compared to benefits
2. Inadequate power
3. Inappropriate allocation of dosages in comparison trials
4. Poor selection and misallocation of participants
5. Midstream changes of protocol
6. Failure to either monitor or record significant adverse events.

متى يحكي انه هذا البحث / التجربة غير أخلاقي؟؟
الموضوع يشمل الأمانة العلمية أيضا بالإضافة إلى سلامة المتطوعين

Point 2

- when conducting a clinical trial with a new treatment and a sample size of 100 participants, it is crucial to ensure that the study is adequately powered. If you include only 50 or 60 participants in each arm, the trial will lack sufficient power to reach statistically significant results. This is unethical because it exposes patients to a new treatment or intervention without yielding reliable data to make informed judgments. Therefore, such a trial should not be initiated.
- Conversely, overpowering a study—including more participants than necessary—is also unethical. For instance, if the trial requires only 100 participants in each arm, including 200 participants would unnecessarily subject an additional 100 individuals to the new treatment and associated investigations. If you plan to include a slightly larger number, such as 130 participants, you must provide a clear and justified rationale for why these additional participants are needed.

Point 5

- you have start clinical trial if you want to make any change in the protocol you must write to the IRB committee who decide that you can do this change or not so it's not you as investigator who decide to make these changes

Point 6

- example, if a trial starts with 100 participants in Arm A and 100 in Arm B, but only 30 participants complete Arm A, it is critical to investigate why the remaining 70 participants dropped out. This could be due to adverse reactions or other factors that directly impact the evaluation of the treatment's safety and efficacy.

- Failing to monitor and document these adverse events is a serious issue. Without this data, the trial may inaccurately approve the study and the medication, leading to its widespread use. This could result in significant adverse events affecting many patients worldwide.

Data Analysis

- An important part of research integrity is the analysis of data.
- It's critical to recognize the importance of appropriate statistical analysis.
- Statistical approaches should be developed as part of the study design.
- If possible, hypotheses should be well defined in advance.

- Current statistical packages permit the mining of entire databases to identify statistically significant results that were not anticipated.
- No statistically significant different is an important result and must be published

- Currently if you want to do any clinical trial we need to register our clinical trial with something we call clinical trials.gov or with WHO clinical trials website why ??

- because previously many clinical Trials were conducted and the results were not published because there was no statistically significant difference between the new treatment and the current treatment in practice no difference is very important result and we should publish that

Efficacy Versus Safety

- Efficacy:Efficacy: maximum response achievable from an applied or dosed agent
- In therapeutic studies, both efficacy of the interventions and their safety are generally studied simultaneously but the design may focus on one or the other 0

Example :
It is important to look at the efficacy at the same time we need to ensure that we have safety profile for this new medication ,if have new treatment for type two diabetes for example and it led significant Improvement in glucose profile control but it led for example to 1 per 1000 or 1 per 300 renal or liver impairment or Anaphylaxis or any major complications so we should balance these things before we approve the medication so safety especially in phase three clinical trials

Appropriate Risk to Benefit Ratio

- Risk is defined as the probability of physical, psychological, social, or economic harm occurring as a result of participation in a research study.
- Both the probability and magnitude of possible harm in human research may vary from minimal to considerable.

- We should consider both things but we should balance benefit versus risk if we think that the risk will be higher than benefit from this new treatment or intervention we should not start the clinical trial

Minimal Harm

- Minimal harm is defined as:

"that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests ".

Eg. Nausea , we accept these minimal harm

Moderate and Maximal Risk

- Risk above this standard is more than minimal (moderate, maximal) and that imposes limitations on the conduct of the research and increases the requirements for monitoring.
- It also requires more stringent approval processes when studying children or otherwise vulnerable populations.
- Increased risk should be accompanied by the probability of appropriately increased benefits.

- In clinical trials, it is crucial to carefully evaluate and report moderate to maximum risks, especially when vulnerable populations, such as children, are involved. Any intervention carrying such risks should only be considered if accompanied by greater potential benefits .
- For example, in cases involving patients with advanced cancer or terminal illnesses, the potential to save or significantly extend a patient's life may justify the risks associated with the trial. However, this balance must be thoroughly documented and reviewed by the Institutional Review Board (IRB) to ensure ethical compliance

Benefits

- Benefit applies to the potential of the research treatment to ameliorate a condition or treat a disease.

- This can apply to an individual participant or to a population.

- In research as in clinical medicine, results cannot be guaranteed but, as a consequence of prior work, a benefit may appear to be a reasonable expectation.

- Since this is research, an advantage for the treatment groups cannot be presupposed.

- Since the risks have not been fully evaluated, a statement of individual benefit should be made most cautiously if at all.

- The investigator should always distinguish between research and treatment and never lure the patient into participating in hopes of remission or cure.

- explanation of the red note

- When planning a Phase 2 or Phase 3 clinical trial, the process begins with seeking approval to conduct the research, guided by a hypothesis that the intervention could be of value to patients. However, it is critical not to present the study to participants in a way that implies guaranteed benefits. For instance, it would be unethical to suggest that the new medication—regardless of whether they are randomized into the experimental or control arm—will provide better control of their disease.

- Careful attention must be paid to the language used when communicating with participants and in all related documentation. This is particularly important in studies requiring an informed consent form, such as cross-sectional studies, cohort studies, case-control studies, or clinical trials involving blood samples or access to patient records.

- The consent form must be worded transparently and accurately to avoid any misleading promises about health improvement or remission of the condition. While participants should understand the potential risks and benefits of the study, the wording must not give false hope or create unrealistic expectations about the study's outcomes.

- حتى ما ينتكسوا في حال ما نجحت او الخ، لا تأملوا المرضى بالشفاء او النتائج العظيمة يلي رح تطلع فيها التجربة،الغريق يتعلق بقشة رفقا بقلوبهم.

Risk Versus Benefit Ratio

- A main role of IRBs is to determine the risk versus benefit ratio for clinical studies.

1. They must make sure that the physical risk is not disproportionate to the benefits.

2. When the physical risk is minimal they must determine that psychological and social risks such as stigma are not important.

3. It is not ethical to conduct a study in which an individual or a group is labeled so as to be stigmatized or to be made less employable or insurable.

Controls

- **Controls** are research participants who receive an **inactive treatment or stay on standard treatment**

- In most trials they are selected by computer lottery from the group of eligible candidates with the condition under study.

- For example
- if you have 300 diabetic or hypertensive patients in the study, each participant must have an equal chance of being assigned to either the new treatment or the standard treatment arm. As discussed in the clinical trials lecture, it is unethical to selectively assign participants to one treatment over another. Every participant should have an equal opportunity to receive either treatment, ensuring randomization and avoiding bias.
- In some cases, a crossover clinical trial may be conducted. This design allows each participant to experience both treatments, which can help strengthen the conclusions drawn from the study.

Normal Controls

- Normal Controls are research participants who **do not have the condition under study.**

- Those taking current treatment according to updated clinical guidelines

types of controls:

1. in cohort studies we have exposure no exposure eg. smokers no smokers controls and uncontrolled.

2. In case control studies we have cases eg. newborns with congenital heart disease controls will be healthy subjects born at the same Hospital during the same period and they don't have congenital heart disease.

3. in clinical trials will be patients taking the standard of care medication and they'll be compared with the patient subjects in the clinical trial who receive the new treatment

Historical Controls

- **Historical controls** are subjects from prior studies or observational investigations whose data are compared with those of the current participants.

- Historical controls were used for years in clinical research and are still sometimes employed because they do not require additional data collection and risk.

- They often produce biases because the research population rarely duplicates the historical population.

- We must avoid historical controls I want to compare patients taking hypertensive medication the new one with the patient who were taking the standard of care previously we said that one of the standards of randomized control clinical trial is that we have random allocation and these historical controls are subjects already taken this intervention previously and you want to compare them with the new intervention they used previously but not anymore and we must avoid them because they might have differences with the control arm and this is why we need to avoid them.

Blinding

- Blinding refers to a process whereby the participant does not know whether he/she is receiving an active agent or a similar appearing inactive substance or mock procedure .

- Blinding is also used in research to refer to investigators who analyze components of a study without knowing the identity and treatment of the participant.

Double Blinding

- Double blinding is a process whereby neither the **investigator** nor the **participant** knows which agent the participant is receiving.
- Usually the research pharmacy holds the master list in case there are complications.
- **Triple blinding: blind the statistician**

Means the statistician doesn't know which treatment each participant received. The data is kept anonymous, and the statistician analyzes it without knowing the group assignments, ensuring unbiased results.

When Blinding is Impossible

- Sometimes the effects of the agent in question are so obvious that true blinding is impossible.
- For example: open versus laparoscopic cholecystectomy

Or Internal fixation Vs cast for fracture

Use of Placebos

- A placebo is an inactive version of a treatment identical in appearance to the real thing. Something looks the same as the studied medication

Note, it's illegal and unethical to useplacebo's. If you have an approved treatment for that condition.

Standard of Care:

- This term applies to the expected care in the medical community as a whole.
- Often, standard of care can be defined on the basis of practice guidelines, which are being developed by all medical specialties, element by eleme

available treatment based on the guidelines, Not your settings.

- The issue of standard of care becomes problematic when a study is to be performed in a developing country where it is impossible to provide medical care at anywhere near the level available in the developed world.
- The current expectation is that controls will be treated at the level of the Western standard of care, not the indigenous standard.

B. Selection of Subject Populations

- Selection of the appropriate participant population plays a critical role in the experimental design.
- They must be selected and dealt with on the basis of the three principles of Human Research, **Autonomy, Beneficence and Justice.**

In clinical trials, it's important to have clear **inclusion and exclusion criteria to ensure every participant has an equal chance to be part of the study.** As an **investigator**, **personal biases should be avoided when selecting participants**, as favoring certain patients (e.g., more cooperative ones) can lead to **selection bias,** which affects study outcomes. Key elements of medical ethics to consider are:

1. Autonomy – respecting the participants' right to make informed decisions.
2. Beneficence – ensuring the study benefits the participants and minimizes harm.
3. Justice – ensuring fairness in participant selection and distribution of benefits and risks.

Protection of Research Participants Who and What?

Who should be involved?

- Individuals involved in the design and/or conduct of human subjects research.

What is the purpose?

- Preparation of investigators involved in the design and/or conduct of research involving human subjects to understand their obligations to protect the rights and welfare of subjects in research.

We should ensure that we are protecting the rights and welfare of the subject in the research we should be clear to the subject that your participation in the study or decision to drop from study at any time will not affect the services that you receive from the hospital or from the clinic

Autonomy

- They should sign the consent informthay they fully understood all the study procedures and treatments in the study

- Autonomy is understood to mean that becoming a research subject is a totally **voluntary act.**
- Individuals must be solicited without coercion or even implied coercion.
- Individuals must be fully informed and understand what they are signing up for.
- IRBs require that the prospective participants understand a long list of things before they can sign a consent document.

Autonomy

- If the study requires a vulnerable population to be studied, (children, cognitively impaired, pregnant women) then a surrogate who, presumably, has their best interests at heart (parent for child, relative for the patient with Alzheimer's disease) must sign for the participant.

- Individuals under the age of 18 are given special protections; so many studies pertain to adults only.
- The rule of autonomy requires that individuals are able to provide informed consent.

we should ensure that certain precaution are taken in these studies, sometimes you have the parents, relative, custodian of the patient will sign on their behalf so we should not exclude them from our clinical at the same time we need to someone there to sign the consent

Goals and Principles of Human Subjects Protection

- Human subjects are essential to the conduct of research intended to improve human health. As such, the relationship between investigators and human subjects is critical and should be based on **honesty**, **trust**, and **respect.**

Historical Events

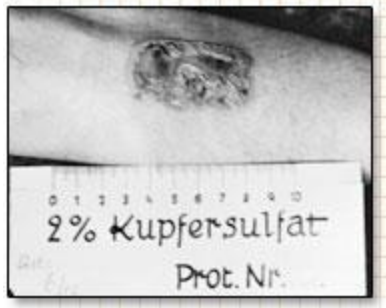
Nazi Medical War Crimes (1939–1945)

actually why we have these ethical regulations worldwide because there were different crimes and misuse of prisoners in some countries and were they used prisoners for clinical trials and this was unethical

- The experiments conducted by Nazi physicians during World War II were unprecedented in their scope and the degree of harm and suffering.

- "Medical experiments" were performed on thousands of camp prisoners and included deadly studies and tortures such as injecting people with gasoline and live viruses, and forcing people to ingest poisons.

- In December 1946, the War Crimes Tribunal at Nuremberg indicted 20 physicians and 3 administrators because they had:corrupted the ethics of the medical and scientific professions and repeatedly and deliberately violated the rights of the subjects



Historical Events
The Nuremburg Code

We need to follow the Nuremberg code in clinical trials

- In the August 1947 the judges included a section called Permissible Medical Experiments.
- This section became known as the Nuremberg Code and was the first international code of research ethics.
- This set of directives established the basic principles that must be observed in order to satisfy moral, ethical, and legal concepts in the conduct of human subject research.

When this code was signed ? 1947

The Nuremburg Code
TEN Directives for Human Experimentation:

1. **Voluntary consent** of the human subject is absolutely essential

2. The experiment must yield generalizable knowledge that could not be obtained in any other way and is not random and unnecessary in nature

   Based on science not randomness. That's why there are protocols and justifications for conducting clinical trials

3. Animal experimentation should precede human experimentation

   That's why there is phase 0 to test it animals before humans

4. All unnecessary physical and mental suffering and injury should be avoided

5. No experiment should be conducted if there is reason to believe that death or disabling injury will occur

The Nuremburg Code (Cont.)
TEN Directives for Human Experimentation:

Risks shouldn't exceed the expected benefits

6. The degree of risk to subjects should never exceed the humanitarian importance of the problem

7. Risks to the subjects should be minimized through proper preparations

8. Experiments should only be conducted by scientifically qualified investigators

9. Subjects should always be at liberty to withdraw from experiments

10. Investigators must be ready to end the experiment at any stage if there is cause to believe that continuing the experiment is likely to result in injury, disability or death to the subject

Key concepts for clinical trials

1. Respect for Persons

1. Respect for Persons

- The principle of respect for persons can be broken down into two basic ideas:

1. **Individuals should be treated as autonomous agents**
   - An autonomous person is able to:
     - Consider the potential harms and benefits of a situation.
     - Analyze how those risks and potential benefits relate to his or her personal goals and values.
     - Take action based on that analysis.

1. Respect for Persons (Cont.)

2. **Persons with diminished autonomy are entitled to additional protections**

- "Special provisions may need to be made when an individual's comprehension is severely limited or when a class of research participants is considered incapable of informed decision making (e.g. children, people with severe developmental disorders, or individuals suffering from dementias).
- In some cases, respect for persons may require seeking the **permission** of other parties, such as a parent or legal guardian."

sometimes we need to have for example some vulnerable subject children people severe development disorders suffering from dementia we need to have someone else to sign on their behalf to take part in the study

Coercion

"Influencing an individual decision about whether or not to do something by using explicit or implied threats (loss of good standing in job, poor grades, etc.)"

for example ask medical student to take part on this if you don't accept I will affect your grades or I'll give you a huge amount of money to take part so this will affect their decision to take part in the study or if you don't take part in the study I don't want to see
you in my practice anymore

Undue Influence

for example if you are offering for the subjects highly attractive rewards like if they joined this clinical trial they'll get 10,000 JDs and participant will try to join the trial although they know that they should could be at risk from The Trial but they will not look at these risk and they will not make a proper decision to take or withdraw from this clinical trial

"An offer of an excessive, unwarranted, inappropriate, or improper reward or other overture in order to obtain compliance"
"excessive compensation"

- Undue inducements are troublesome because:
  - offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and
  - they may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling — or continuing — as participants in a research project ".

Undue Influence versus Compensation

- Some types of research involve a significant commitment from research participants in terms of time or effort, and investigators may wish to provide compensation .
- Institutions should consider establishing standards for fair and appropriate compensation .
- Compensation is meant to reimburse research participants for their time, research-related inconveniences and/or research- related discomforts
- <u>Compensation is not a benefit of the research.</u>

compensation is not a benefit of the research it's just to credit participants for their time about for example transportation , or Prizes the end of the trial but **this should be something that will not influence participation in the trial** , in many country worldwide we just provide subjects with compensation mainly for transportation if the clinical trial involves for example in some clinical trials that patient have certain cognitive testing or reactive times takes two three hours, we might compensate them for their time

not compensate them to **encourage them to take part in the study** these are two different things but overall we need to try to avoid these compensations ,however,**Transportation** is acceptable.

Informed Consent

most Medical epidemiologiccal studies (cross sectional studies case control cohort clinical trials) we should ensure that we have a consent form sometimes .
consent form is not recommended for surveys we don't ask about any identifiers we are asking about opinions attitudes beliefs knowledge personally I don't encourage the consent form these cases

but I should not be the one who decide that it's no consent form it's the Ethics Committee who decide on the consent form if you are going to collect **blood sample if you want to get permission for the subject to review their medical notes if you are giving them new treatment or testing them** any **clinical trial you should have a consent** form sometimes there's debates on some cases of surveys cross **sectional studies but in cohort studies case control studies clinical trial we** must have informed consent and subject should sign it voluntarily

- Definition: A **legally-effective, voluntary agreement** that is given by a prospective research participant following comprehension and consideration of all relevant information pertinent to the decision to participate in a study.

- The HHS regulations require that investigators obtain legally effective informed consent from prospective participants in a way that allows them to consider whether or not to participate and that minimizes the possibility for coercion or Undue influence.

Voluntariness

- Individuals' **decisions** about participation in research should **not be influenced by anyone involved in conducting the research**: "…consent must be freely given or truly voluntary."

Comprehension تعويضات

- Individuals must have the **mental or decisional capacity to understand** the information presented to them in order to make an informed decision about participation in research.

Disclosure

Disclosure : Providing participants with full details about the study, including its purpose, risks, benefits, and their rights (e.g., through an informed consent process).

Example: Disclosing potential risks of a medication being tested in a clinical trial.

Why should we have

- Researchers must disclose:

1. The **purpose** of the study
2. Any reasonably foreseeable **risks** to the individual
3. Potential **benefits** to the individual or others
4. **Alternatives** to the research protocol

you should emphasize that for example often we have the study that will help others not you as a participant

5. The extent of **confidentiality protections** for the individual
6. **Compensation** in case of injury due to the protocol
7. **Contact information** for questions regarding the study, participants' rights, and in case of injury
8. The **conditions of participation**, including right to refuse or withdraw without penalty

- This disclosure must be made in such a way that it provides a reasonable person the information she or he would need in order to make an informed decision.

Point 6 explanation:

It is essential to have insurance coverage for the study to address any harm that may arise, whether due to the study medication or travel to the study center. Participants should be compensated for any harm, including both negligent and non-negligent harm. Most Institutional Review Boards (IRBs) require insurance documentation as part of the study approval process. Additionally, consent forms should include:

1. Contact Information: Clear details for participants or their caregivers to report injuries or complications related to the study.
2. Participant Rights: A statement emphasizing that participants are free to join or withdraw from the study at any time without affecting the standard care they are entitled to receive at the hospital or study site.

These elements ensure ethical compliance and protect both participants and the study team.

Participation of Pregnant Women in Research

- It is essential to prohibit:
  - Inducements of any kind to terminate a pregnancy.
  - Investigators from taking part in decisions about terminating a pregnancy.
  - Investigators from determining the viability of a neonate.

Children's Participation in Research

That's why we have someone to sign on their behalf

- Children may not have full capacity to make decisions in their own best interests; and therefore :
  - Children are considered a vulnerable population, and
  - Children are unable to provide "legally effective informed consent "

- Because children cannot provide informed consent, children provide assent* to participate in research, to the extent that they are able, and parents/guardians give permission for a child to participate in research .

* Assent: affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent."

Excluding Children From Research

- The NIH Policy and Guidelines on the Inclusion of Children in Research states that children must be included in all NIH-supported human subjects research unless "… there are scientific and ethical reasons not to include them".

Children should not be excluded from research, particularly when it involves new treatments such as antibiotics for bronchial asthma, cancer, or other medical conditions. Conducting clinical trials involving children is essential to improve their health outcomes. However, their inclusion must adhere to strict ethical standards.

Since children cannot fully make decisions about their participation or evaluate the balance between risks and benefits, a responsible guardian or legal representative must provide consent on their behalf. These safeguards ensure that the research is conducted responsibly while addressing the unique needs of pediatric populations.

Obtaining Informed Consent From Prisoners

we should ensure that we have consent form and I need you all to look at the samples that I'll provide you with to see how we can write the consent form for our research

- Requirements specific to informed consent for prisoners are:

- Not to be under constraints as a result of their incarceration that could affect their ability to make a truly voluntary decision about whether or not to participate in research.

- Adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her

2. Beneficence

2. Beneficence

ensure that we maximize benefit but without promises actually the key idea of doing research we have potential benefit for the subjects to control their blood pressure to control to reduce their asthmatic episodes for example to improve the quality of life of cancer survivors to reduce mortality so we need to ensure these things

Two general rules have been articulated as complementary expressions of beneficent actions:

- Do no harm.
- Maximize possible benefits and minimize possible harms.

The challenge inherent in applying the Belmont principle of beneficence is how to determine when potential benefits outweigh considerations of risks and vice versa.

Privacy and Confidentiality

Investigators are responsible for

- Protecting privacy of individuals.
- Confidentiality of data .

  - Privacy means being “free from unsanctioned intrusion”.

  - Confidentiality means holding secret all information relating to an individual, unless the individual gives consent permitting disclosure.

Sometimes when send blood samples We don’t write any identifiers instead participants Study code and date of birth to ensure confidentiality

Coded Private Information and Human Subjects Research

Dont use a sample with consulting the subjects

- Research with coded private information or specimens does not involve human subjects if:
  - The private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and
  - The investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens

Case Study: Research With Anonymized Data

Coded data : No name / identifier of the subject

- You are an investigator proposing to use data from a colleague's database to conduct secondary analyses. Your colleague will provide coded data for your proposed studies, and you and he enter into an agreement by which he will keep the key to the code and will have no other involvement in the research.

- Does this study involve human subjects?
- Yes, this study involves human subjects .
- No, this study does not involve human subjects .

When conducting secondary analysis, a consent form is generally not required if there are no identifiers linked to the subjects and the research does not involve direct interaction with human participants. This is because the work involves analyzing de-identified data from a database, not handling human subjects or their biological samples directly.

However, if you plan to use biological samples from a previous study for further analysis, such as testing for antibody levels in a study initially focused on the prevalence of hypothyroidism in Jordan, the original consent form must include a clause allowing for future research use of the samples. This clause should state that the samples may be used for additional research without identifying the participants, ensuring confidentiality.

Additionally, IRB approval is still required to conduct the secondary analysis on these samples, even if participants' identities remain protected. This ensures the study complies with ethical standards and regulatory requirements.

Anticipated Benefits Greater than Potential Harms

- Research requires that:
  - Risks are minimized
  - Unavoidable risks are justified as necessary for sound scientific design
  - Research studies are anticipated to make progress toward important, generalizable knowledge

Institutional Review Boards(IRB)

- IRBs determine:
  - “the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice ”

We have here at the unineversity of Jordan. An IRB committee in most hospitals and is care organisations.

3. Justice

3. Justice

- Justice requires that individuals and groups be **treated fairly and equitably in terms of bearing** the burdens and receiving the benefits of research.

- The principle of justice may arise in decisions about inclusion and exclusion criteria for participation in research and requires investigators to question whether groups are considered for inclusion simply because of their availability, their compromised position, or their vulnerability — rather than for reasons directly related to the problem being studied .

And each subject should have equal chance to be in the study.

Justice

- Justice relates to access to research of all relevant populations specifically including age, ethnicity, gender and preexisting conditions.

- Several countries have made it clear that studies should try to include ethnic groups and women in proportion to the population in the community unless there is a good scientific reason not to (for example studying hypertension in African Americans).
- Issues that must be considered in justice determinations include:
  - Socioeconomic Status
  - Gender,
  - Race,
  - Age,
  - Existing medical conditions
  - Vulnerable populations (as noted above)
  - Determining ability to consent
  - Ensuring understanding of protocol
  - Appropriate surrogate for consent
  - Coercive nature of relationship (prisoners)
- The need to use such populations must be justified

we mentioned previously slide 40 undue influence that if we provide huge amount of money that this will be something lucrative and enhance the point for subjects to join the study without looking at the risk of from taking part in that study

Equity vs. Equality in Human Subjects Research

- The meanings of “equity” and “equality” are similar, but not the same.

To treat“ equitably ”means to treat fairly;
To treat“ equally ”means to treat in exactly the same way.

for example

- **Equally** patients with breast cancer stage three they should have equal chance to have *same* access for available treatments.
- **Equity** is different thing you are sitting at the emergency department and you have two patients coming at the same time **patient A** with upper respiratory tract infection **patient B** with MI I should start with the patient with a MI this is equity not equality we should balance these things

for example

- I have a cross-sectional study on certain illness that the prevalence of females are three times higher than males I have three times sample from female population and this is **equity**

Case Study: Migraine Intervention Trial

- A researcher seeks to improve treatment for severe migraines that are partially responsive to oral medication. He proposes to test whether acupuncture, in addition to a sufferer's oral medication, is more effective treatment than oral medication alone. Because women are three times more likely to experience migraines than men ,he proposes to enroll three times as many women as men. They will be recruited from racially and ethnically diverse communities .

- Does this study design fulfill the principle of justice?

- Yes, this study design does fulfill the principle of justice
- No, this study design does not fulfill the principle of justice

Is he following the principle of justice?
Yes he is because he did not exclude men and we know that females are three times higher than males

Yes, this Study Design Does Fulfill the Principle of Justice

Correct!

This is what we call satisfaction and we discussed this previously in the sampling technique

Stratification in sampling

- The research includes women and men in proportion to the rates of severe migraines experienced by each sex, and is designed to have racial and ethnic diversity.
- The study provides both sexes and racial/ethnic communities with the opportunity for benefits from the clinical trials ,and does not unfairly burden any single group with the risks of research. Its design is fair .

Justice and the Use of Placebos

- A researcher's duty is not to exploit or deceive* research participants and to treat them fairly.

- The informed consent process must disclose sufficient information to ensure that potential research participants:
  - Understand what placebos are
  - Understand the likelihood that they will receive a placebo
  - Are able to provide their fully informed consent that they are willing to receive a placebo

*Misleading research participants about the research purpose or procedures

When we use placebo, we need to ensure that first of all, there is no existing standard of care and then **subject to fully understand that there are equal chances to take the placebo or the active treatment,** and we need to maintain blinding and make sure they are willing to accept a placebo


Investigators should allow Individuals to make their own decisions
Investigators should design research studies as to maximize benefit and minimize risk to individuals
Individuals who are less able to take decisions for themselves require additional protection
The burdens and benefits of research should be fairly distributed among individuals and society
Justice
Respect
Beneficence

https://youtu.be/8DRzaZiI8EuHtUZo=is?Q_8bqjB89vX
https://youtu.be/LeAZ4EGEx7w?si=kipkqe8I6hU2oxhE

VERSIONS	SLIDE #	BEFORE CORRECTION	AFTER CORRECTION
V1→ V2			
V2→V3			

امسح الرمز و شاركنا بأفكارك لتحسين أدائنا !!