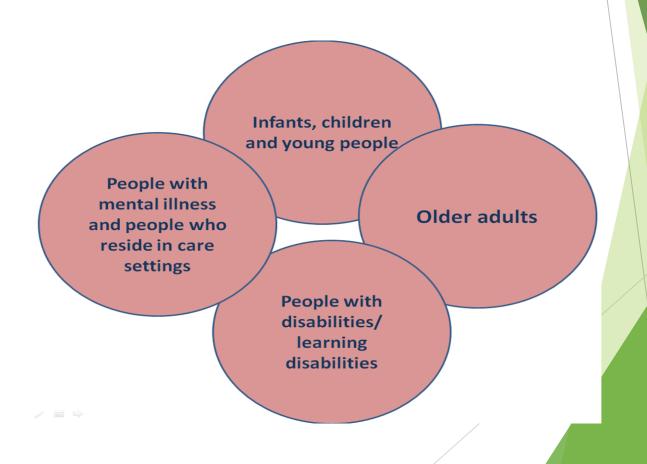
### Research on human:

- Experimental study: For example, in a clinical trial of a new vaccine, the investigator may randomly assign some of the participants to receive the new vaccine, while others receive a placebo shot. The investigator then tracks all participants, observes who gets the disease that the new vaccine is intended to prevent, and compares the two groups (new vaccine vs. placebo) to see whether the vaccine group has a lower rate of disease.
- Observational study: the epidemiologist simply observes the exposure and disease status of each study participant. Example: cohort studies
  - ▶ **Prospective study:** Informed consent will be taken from patients. In case of incompetent patients, the informed consent will be taken from the guardians.
  - ▶ **Retrospective study:** Confidentiality of records will be considered
- ▶ All drugs used in the research are approved by the Ministry of Health

**VULNERABLE SUBJECTS:** sub-segment of the general public requiring maximum care and particular special protections in research. Vulnerable population require close and careful attention during the clinical trial design with high quality observation methods of overall safety and efficacy strategies ensuing research



## Children:

- In addition to the roles that followed in adult ones; the following should be done:
  - ▶ If the research is not applicable on adult.
  - ► This age group should gain the benefits of the results of the research.
  - ▶ Consent is obtained from the guardians.

## Pregnant and lactating women:

- Consent is obtained from wife and husband.
- Inability to perform the experiment in non-pregnant women.
- ▶ Benefits of the research focus on this group.
- No risk to the infant and children.

## **Prisoners:**

- ▶ Prisoners must obtain full medical care.
- Consent.
- ▶ Do not use any collected data against the prisoners.
- ► Have the full rights as free person

## When to stop the research

- It is impossible to reach the main aim of the research.
- ► Endanger the life of the participants.
- ► The risk of the research is much more than its benefits.

## Ethics of stem cell research

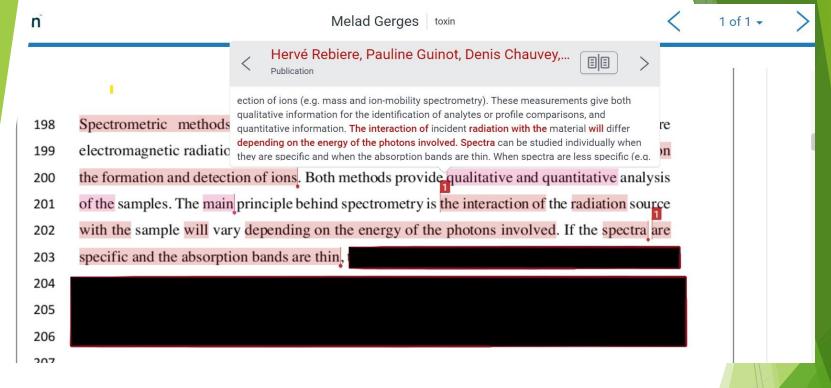
- ► Source: embryo or adult
- Consent of mother for cord blood should be taken
- Consent from couple in spare embryo should be taken
- Should be used in treatment only not for cloning

## Areas of Academic misconduct

- 1. Plagiarism
- 2. Fabrication
- 3. Falsification
- 4. Non-publication of data
- 5. Faulty data-gathering procedures
- 6. Poor data storage and retention
- 7. Misleading authorship

## Research misconduct

- Fabrication is making up data or results and recording or reporting them.
- Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results.
- Plagiarism is the use of another person's ideas, processes, results, or words without giving appropriate credit and presenting them as your own.



## PLAGIARISM CHECKER: as turnitin

## Non-Publication of data

▶ Data not included in results because they don't support the desired outcome

## Authorship...

Misleading authorship—who should be an author?

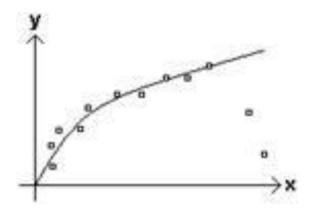
- Technicians do not necessarily become joint authors.
- Authorship should involve only those who contribute directly.
- Discuss authorship before the project!
- Publication of the thesis
  - Should be regarded as the student's work
  - ▶ Students should be listed as primary authors
- ▶ Dual publication a manuscript should only be published in a single journal
- ▶ Proper and complete referencing is an essential part of any research publication.
- ▶ Deliberate omission of an author or reference is unethical and unacceptable.

## Ethics of clinical trial & drug development

- 1. experimentation on animals at first (preclinical study).
- 2. Follow 4 phases:
- ► Phase I:Healthy volunteers (10-80)
- ▶ Phase II: Diseased (100-300)
- ▶ Phase III: Diseased (1000-3000)
- ▶ Phase IV: After license and marketing

## Case 1

Two graduate students have made some measurements on a new material. The data points are as shown. To prove their hypothesis the results should lie on the curve shown. The two students considered omitting the two data points which were off the theoretical curve.



•	Unethical as it would amount to falsification of data	
	Should include outliers and give probable reasons or find out statistically acceptable ways of trimming outliers	

### case 2

A group of medical students conducted a research on the awareness of diabetic diet in medical clinic participants. Their research was recognized as the best undergraduate research and later they submitted the same research paper to two different journals to see which journal publishes it first.

Unethical as it would result in "inadvertent double-counting or inappropriate weighting of the results of a single study, which distorts the available evidence

-it would give a false idea of the number of publications in a given area

-wasting of resources on the review and process

publication

Should submit to one journal and wait for response prior to submitting to another



## **Ethics of Organ Transplantation**

Dr Melad Gad Paulis

Like 7 Share Tweet

عيات خيرية

كز الدراسات والأبحاث

لمات مجتمعية وحقوق الانسان

ات عمالية

ات خاصة



لمات أصحاب العمل

لمات مهنية

لمات متخصصة

لمات أجنبية

مجة وتصميم MENA CIRCLE



منظمات الرعاية الصحية »

سنة التأسيس: 1987

الاهداف: تشجيع المواطنين على التكافل فيما بينهم لتخفيف المعاناة التي قد يسببها فقدان احد أعضاء جسم الإنسان، وتشجيع أولياء أمور الأفراد الذين توفاهم الله للتبرع بالأعضاء التي يمكن أن يستفاد منها في إنقاذ حياة إنسان آخر أو تحسين نمط حياته و هذه الأعضاء هي ( القلب، الكليتين، القرنيتين)، وإبراز مدى أهمية التبرع بالأعضاء لدى المواطنين من خلال قيام الأطباء المختصين و علماء الدين و قادة الرأي في المجتمع بإعداد المحاضرات الخاصة في هذا المجال، ودعم البحوث العلمية المتعلقة بزراعة الأعضاء والعمل على إبراز النماذج الحية المجسدة لأهمية التبرع بالأعضاء من خلال القيام بحملات إعلامية بمختلف الوسائل.

عدد الاعضاء: 80 عضو

الفروع: لا يوجد

رئيــس: الأمير رعد بن زيد

أعضاء الهيئة الإدارية: نائب الرئيس: احمد جميل.

أمين السر: رانيا جبر القرم.

أمين الصندوق: أديب عكروش.

مدة الدورة الانتخابيـة: 3 سنوات

تاريــخ آخـر انتخابات: 2016

## Statistics in Jordan 2019

- Organ donations from living donors in the Kingdom account for 99 per cent of total donations and only 1 percent come from brain dead persons
- 175 organ transplant operations were performed in the Kingdom last year, both for Jordanians and non-Jordanians, including 160 kidney transplants and 15 liver transplants.

## Organ transplantation

- An organ transplant is a surgical operation in which a failure or damaged organ in human body is removed and replaced with a functioning one. The donated organ may be from a deceased donor, a living donor or an animal.
- Organs that can be transplanted are the heart, kidneys, liver, lungs, pancreas, intestine and thymus.
- Tissues include bones, tendons, cornea, skin, heart valves, nerves and veins.
- Worldwide, the kidneys are the most commonly transplanted organs, followed by the liver and then the heart.

# Legal rules have been followed before blood transfusion

The first discussion of this issue was on starting <u>blood</u> <u>transfusion</u> early in the twentieth century. when a person looses blood due to an injury, a blood disease or during surgical interference.

### **Conditions**

- No alternative method of treatment
- No harm or damage to the donor
- Consent of the donor
- Under medical supervision
- The donor should be clinically free from a transmissible disease

- Organ transplantation has been widely known in the mass media as offering new hope for thousands of ill patients.
- The major clinical problems include
  - tissue rejection
  - organ preservation
  - insufficient facilities and manpower
  - and the high cost of each operation
  - The law has an additional restriction
  - Community

## Sources of organ

- CADAVERIC ORGAN DONATION Organs taken from deceased people are called cadaveric organs. Cadaver is Latin for "a dead body." A person becomes a cadaveric organ donor by indicating that they would like to be an organ donor when they die. This decision can be expressed either on a driver's license or in a health care directive.
- LIVING ORGAN DONATION Living people who wish to donate their organs can donate in two ways:
- 1. Donate one-half of a paired organ set. Example: Kidney
- 2. Donate a portion of an organ that will still be able to function without it. Example: A portion of the liver. Example: A lobe of the lung

## Types of organ transplantation:

- Classification of organ transplantation:-
- I) <u>Auto-transplantation:</u> (to him or back to him)
  - It involves the transplantation of tissue from one individual back to the same individual (e.g., skin, teeth, hair...etc).
- l) <u>Isograft:-</u> Graft=Transplant (Between genetically identical individuals)
  - Donor and recipient are genetically individuals of the same species, such as graft between monozygotic twins.
- I) Allo-transplants:- (genetically different ones)
  - Transplants from one individual into another genetically different one, it including cornea, teeth, bone....etc.
- I) Xenograft:- (between different species)
  - Where grafts between different species have been performed in the part for skin & heart valves.

# Transplantation from a living person to another living one

- There should be no harm or danger on the donor's life.
- The operation should be done in a recognized hospital.
- -The donor should be related to the recipient up to the third degree, so as to prevent selling organs



# Transplantation from a dead to a living

- The importance of brain death appeared in recent years.
- It is the irreversible cessation of all brain function including the brainstem. When the brain cells die, they do not grow back, thus any damage is permanent and irreversible function.



Nowadays modern resuscitative devices and techniques can maintain the function of the heart, lungs & visceral organs for a period of time after the brain stem centers have stopped



The development of transplant surgery and the need of viable organs have resulted in the need for accurate determination of the medical criteria of brain death.



## The medical criteria of brain death

☐Know cause of coma: structural brain damage	
☐ Exclusion of revisable causes of coma as toxic or metabolic.	
■No hypothermia: temp more 35.	
☐Absent brain stem reflexes:	
☐No motor response within cranial nerves areas.	
☐No pupillary response to light.	
□No corneal reflex.	



- ☐ No oculovestibular reflex.
- ☐ No oculocephalic reflex
- ☐ No gag reflex
- ☐ Apnea test



## **the rules** that should be followed are:

- 1.Death certificate should be signed by three physicians of good qualification and not from transplant team.
- 2.The dead person should have given a will وصية before death or permission for transplantation.
- 3.Consent of his relatives.

These rules are put to prevent abuse and loss of confidence in physicians.



## THANK YOU

