WHAT MAKES RESEARCH ETHICAL?
The 8 principles of ethical research

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Content

- History of unethical research practices
- What makes research ethical
- Elements of Review by an REC
  - Analysis of risk and benefit
- Trust and competency in research

Please watch this video

https://www.youtube.com/watch?v=vz4jE7huhMA

Brain storm (10 Minutes)

- Were the population in Tuskegee experiment Vulnerable? If yes, why?
- What are the ethical concerns raised in this study?

Evolution of Codes, Guidelines, and Regulations

Codes of ethics and declarations were passed at different times in response to the discoveries of the tragic consequences of unethical research.

What makes research ethical?

- Respect/protection of subjects
- Beneficence/Nonmalficence (Reasonable risk/benefit)
- Justice

Belmont Report

Putting principles into action

- IRB Review
- Social value
- Community Partnership
- Scientific validity
- Risk/Benefit evaluation
- Ensure autonomy (informed consent)
- Respect for enrolled subject
- Ensure Justice

Adapted from Dr Silverman's presentation

Step 1 IRB review

- **Which of the following is NOT true of Research Ethics Committees?**

Please Select one:

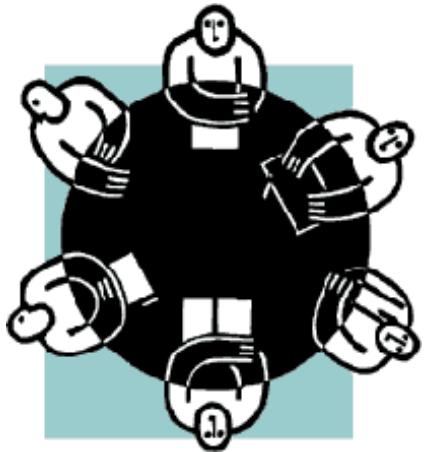
a. RECs usually have between 5 and 14 members

b. Membership of RECs are multidisciplinary

c. At least one member is a non-scientist

d. At least one member is a representative from the community

e. At times, the decisions of an REC may be overturned by the President of the University



Case study

Dr. Salah and his team are planning to submit an research proposal to study the genetic factors in donors and recipients that predict transplant success. Dr. Salah is also a member in the REC in the same university.

Can Dr. Salah vote on this proposal?

IRBs must review research proposals to ensure that the research is ethical

Step 2 Social Value

Dr. Hind wants to do an epidemiological study on the prevalence of Methicillin- Resistant infections on patients admitted to the ICU in a large hospital. She wants to perform testing on left-over blood and sputum samples obtained originally for clinical purposes to identify culture and sensitivity of combination of antibiotic therapies.

Does this study have a social value?

Can informed consent be waived for use of left over annonymous samples?

Step 2 Social Value
Case study

DR. Mohamed, an Egyptian researcher, plans to join an International study of a Phase 1 safety study for a drug designed to reduce the damage from severe frost bite undertaken on healthy individuals who are exposed to extremely low temperature?

Does this study have a social value in Egypt?

The results of research should potentially promote the future health of society in which the clinical trial was undertaken

Step 3 community Partnership

In Egypt, a study is conducted to assess the Knowledge, attitudes and perception of water pipe smoking (Shisha) among adolescents aged from 14-19 years.

How can we engage the community in such research???

(Think pair and share 5 minutes)

To be ethical research must be responsive to the needs of the community and hence, human subject research should involve the community in which it occurs.

Step 4 Scientific validity

Dr. Hassan, a member of the REC in x university, was reviewing a study and noticed that the sample size of the proposed study is small. This small sample size can compromise the scientific validity of the study.

In this case, should Dr. Hassan accept undertaking the study as such?

To be ethical, research must be conducted with an appropriate **methodology** to ensure that the results will answer the original research questions.

Step 5
Risk/Benefit

Dr. John has proposed a study to treat Alzheimer disease with drug X. This drug has shown some promising results in animals. However this drug is highly toxic, resulting in a mortality 20% at the dose Dr. John is proposing. Participants are willing to participate and will sign an informed consent.

What is the ethical concern in this study?

Case Study

- Dr. John has proposed a study to treat an infectious disease, which is spreading rapidly and has >80 % mortality with drug Z. This drug has shown some promising results in animals. However this drug is highly toxic, resulting in a mortality 20% at the dose Dr. John is proposing. Participants are willing to participate and will sign an informed consent.

Should this study be allowed to proceed?

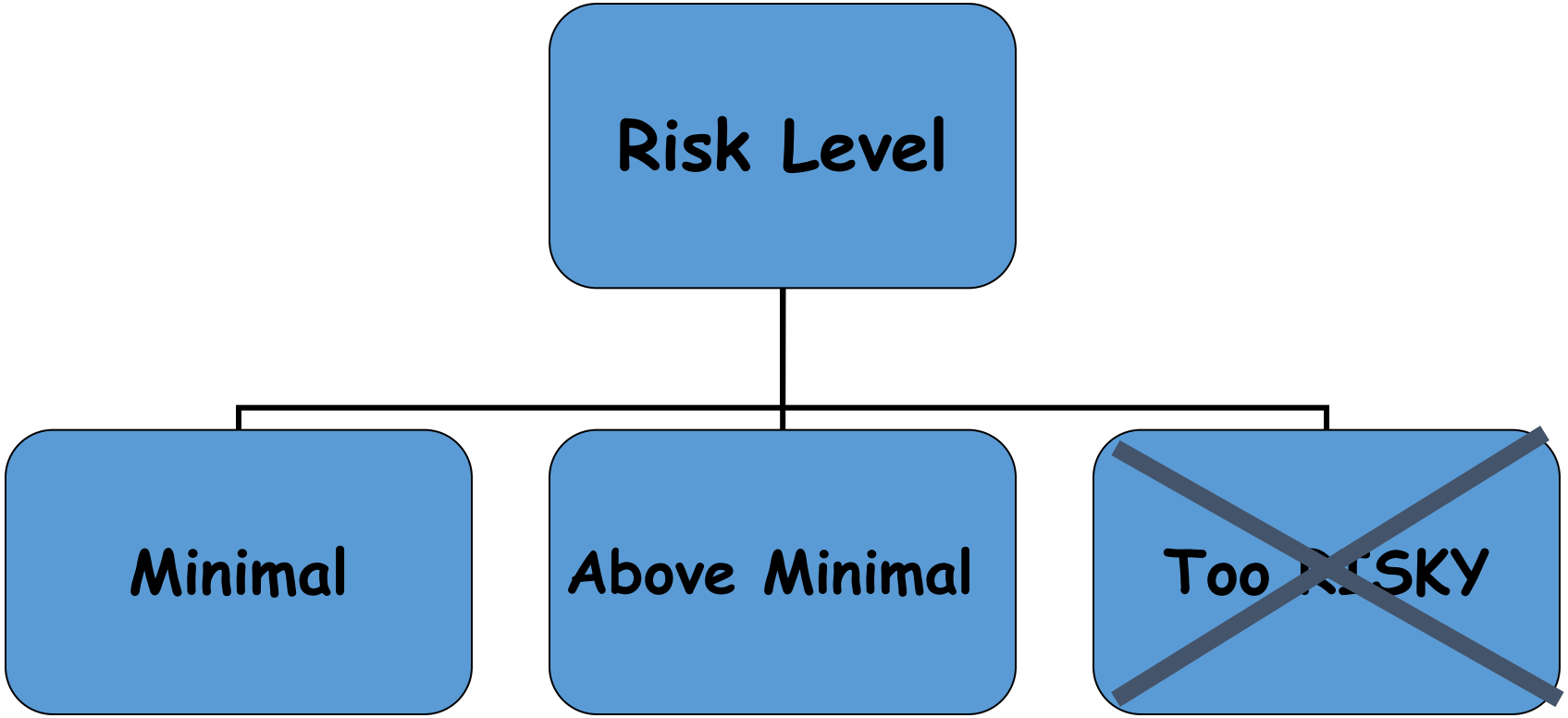
Analysis of Risk I
Risk Fractionation

What are the different types of risk you can think of?

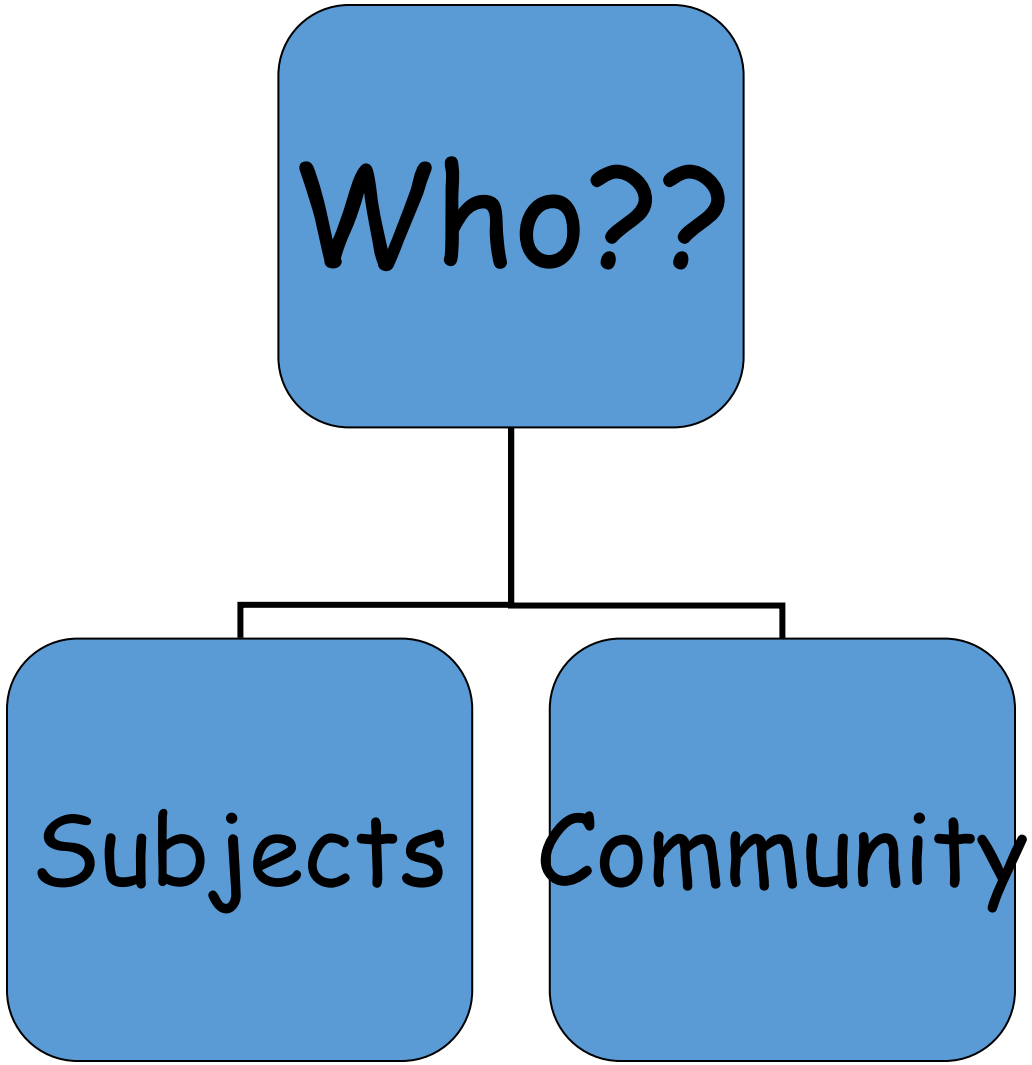
Think pair and share

(10 minutes)

Analysis of Risk II
Level of Risk



Analysis of Benefit



Case study

Dr. Ramy is proposing a study to treat Multiple Sclerosis disease. A Phase 1 safety study was conducted and the maximum tolerated dose was identified. He is proposing to proceed to phase two study to access efficacy. He is offering to closely monitor MS patients during the whole study and will compensate them for all the transportation expenses. Dr. Ramy will also give them 200 L.E /follow up visit. Several patients have already indicated that they are willing to participate in this trial.

Identify different types of benefits;

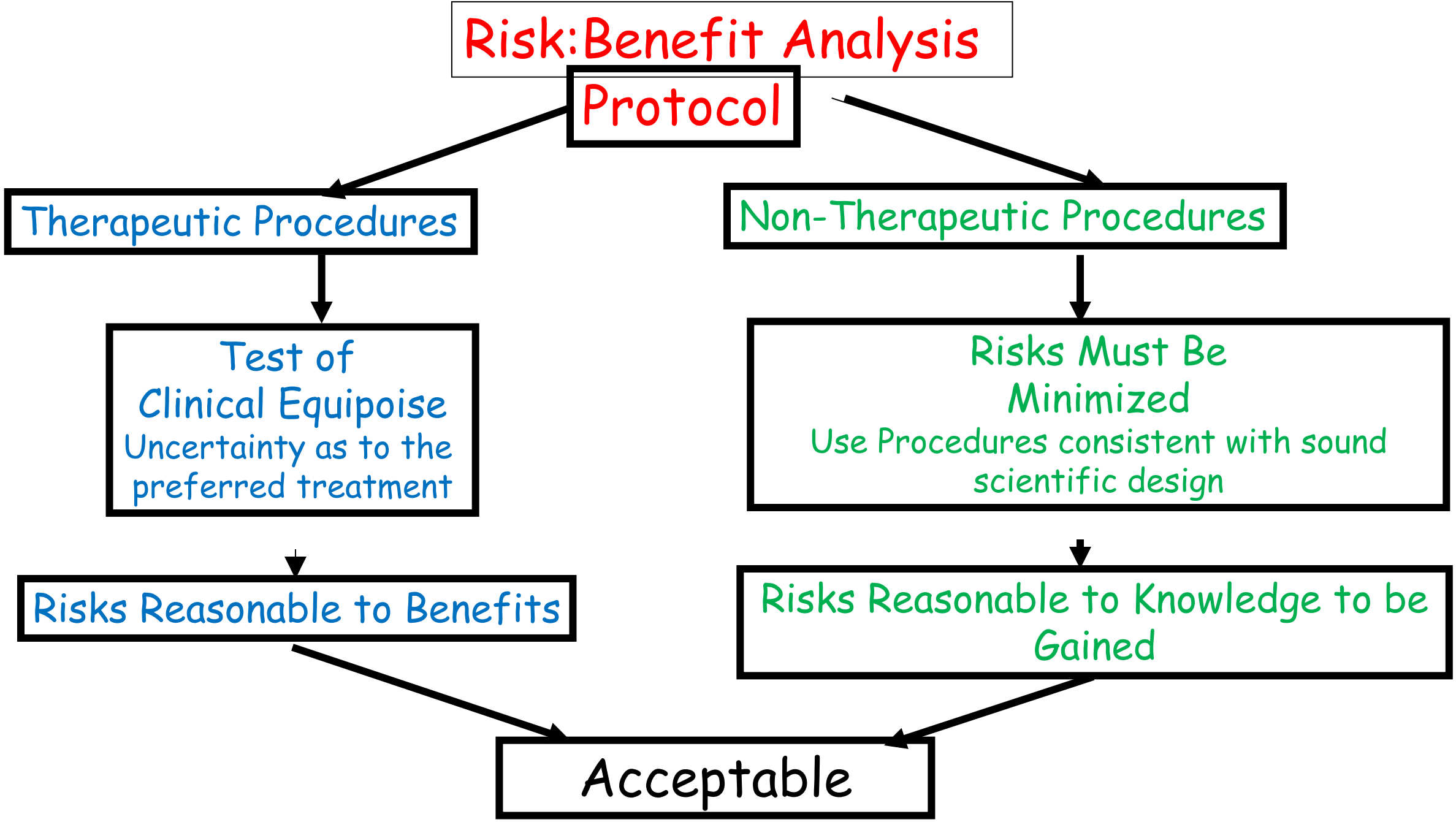
Direct benefit- collateral benefit – Benefit to society

Include incentives in risk benefit analysis????

YES **NO**

We SHOULD NOT

- Skew judgments concerning risks and potential benefits
- IF included: Benefit side could outweigh Any level of research risk


Risk:Benefit Analysis
Protocol
Therapeutic Procedures
Non-Therapeutic Procedures
Test of
Clinical Equipoise
Uncertainty as to the
preferred treatment
Risks Must Be
Minimized
Use Procedures consistent with sound
scientific design
Risks Reasonable to Benefits
Risks Reasonable to Knowledge to be
Gained
Acceptable

Reasonable Risk/Benefit

Potential risks and benefits to individuals are compared and an assessment is made that the risks are reasonable to the potential benefits.

Step 6 Subject respect: Autonomy
Informed Consent Process

- Content
- Understandability
- Documentation

Activity

GROUP DISCUSSION:

DISCUSS THE BASIC ELEMETS OF THE INFORMED CONCENT

Basic elements of informed consent

1. A statement that the study involves research
2. A description of the procedures to be followed
3. A listing of any reasonable foreseeable risks or discomforts to the participants
4. A statement that participation is voluntary and that individuals can refuse to enroll in the clinical trial.
5. Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participants
6. A statement that withdrawal can take place anytime during the study without stating any reasons.
7. A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained

Step 7 Respect of the enrolled subjects

GROUP DISCUSSION:

Dr. Amal is proposing a research project to investigate the social aspects of HIV in Egypt. Dr. Amal understands that the data she possess is highly confidential. Accordingly, she proposes to the REC to store all the data on her personal laptop which is secured by a password only known by her.

Are these protective measures enough? If not, What else can she do?

Step 8 Ensure Justice

Unemployed illicit drug users were approached to participate in a study to investigate a new anti hypertensive drug. They will be paid 300 L.E/visit. They will be checked biweekly for a period of 3 months. The visit includes measuring the blood pressure and withdrawal of a blood sample.

Should the IRB approve this study?

Trust and Competency

- REC DO NOT hinder research but help researcher to conduct research ethically
- Protection of: participants/researchers/institution/society
- Management of conflicts of interest
- Mutual benefit in case of multi-center/ international research
- Building up of TRUST between the public and the research team
- Transparency among all parties involved !!!!!!!!!

Group activity: Willowbrook Case+ IC

Role play of REC review through group of 5 acting as REC followed by whole class discussion

Resources

- WHO Guidelines
- Belmont Report
- CIOMS
- HRETIE Program
- Declaration of Helsinki (WMA 6th revision 2008)
- ***Emanuel E, Wendler D, Grady C. What Makes Clinical Research Ethical? Journal of the American Medical Association 2000;283(20):2701-2711 @***