

Ethics



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South African Medical Research Council

BUILDING A HEALTHY NATION THROUGH RESEARCH





History

- Horrific medical & scientific experiments throughout history.
- Terrible experiments, e.g. on prisoners of war in World War II.
- Then countries around the world committed to ethical principles to guide research & experiments in humans.
- To stop abuses & violations happening again.
- Principles recorded in international & national documents, e.g:
 - *Declaration of Helsinki*
 - *Guidelines on ethics in health research (DoH)*



What is ethics?

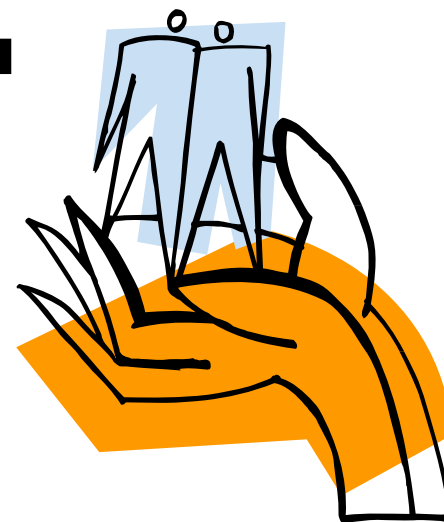
- The study of the principles & rules that we use to:
 - decide which actions are acceptable & which are not, and
 - guide our behaviour in relationships with others.
- Ethics is concerned with what is right, fair & just.





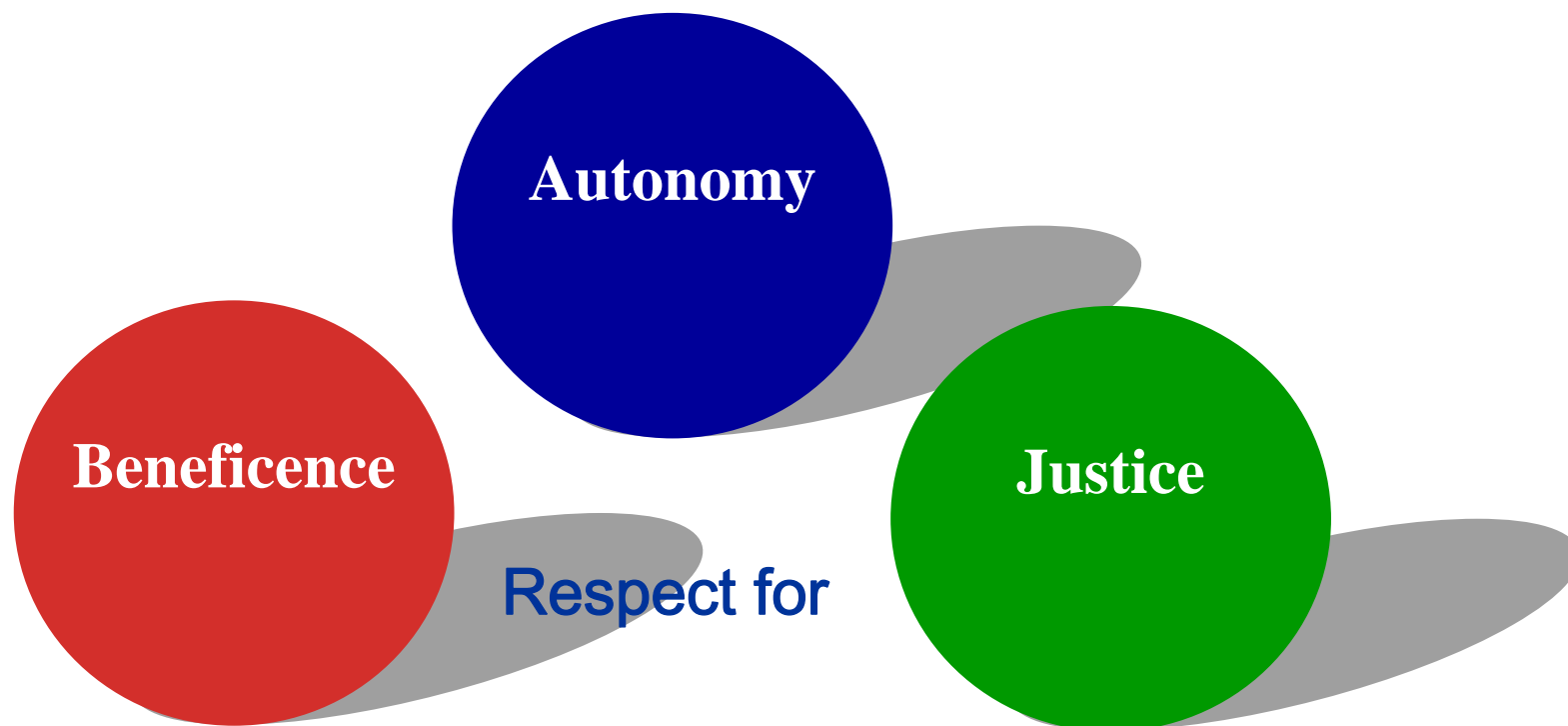
Why is ethics important in HIV vaccine trials?

- So that we:
 - treat people with dignity & respect.
 - protect the rights & welfare of trial participants.
 - protect their well-being & safety.
- To advance scientific knowledge without harming volunteers.





Three main ethical principles





- To respect a person's right to independently choose & act.
- Researchers must:
 - Give enough information & the freedom to choose.
 - Take special measures to protect vulnerable people & communities.

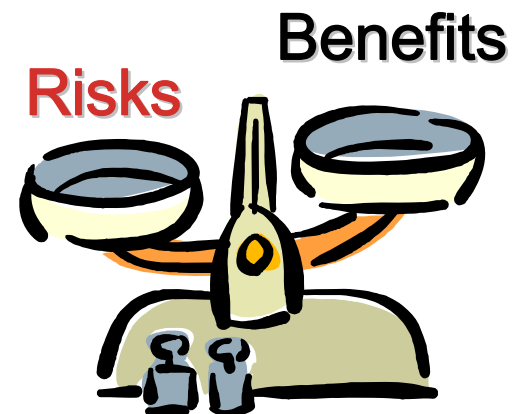
A large blue circle with a white shadow to its right, containing the word 'Autonomy' in white text.

Autonomy



Respect for beneficence

- Taking active steps to minimise risks & maximise benefits.
- Balancing benefits & risks.
- Do no harm.
- Risks to individual should be outweighed by benefits to them and/ society.





Respect for justice

- To distribute benefits & risks of research fairly.
- Treat people according to what is right, fair and just & each one should get what is owing to him or her.
 - e.g. rich should pay more tax than the poor
- Marginalised people should not be further exploited.
- Injustice occurs when:
 - a risk is unfairly forced onto a person, & or
 - when a benefit is unfairly denied.





Respect for justice in research

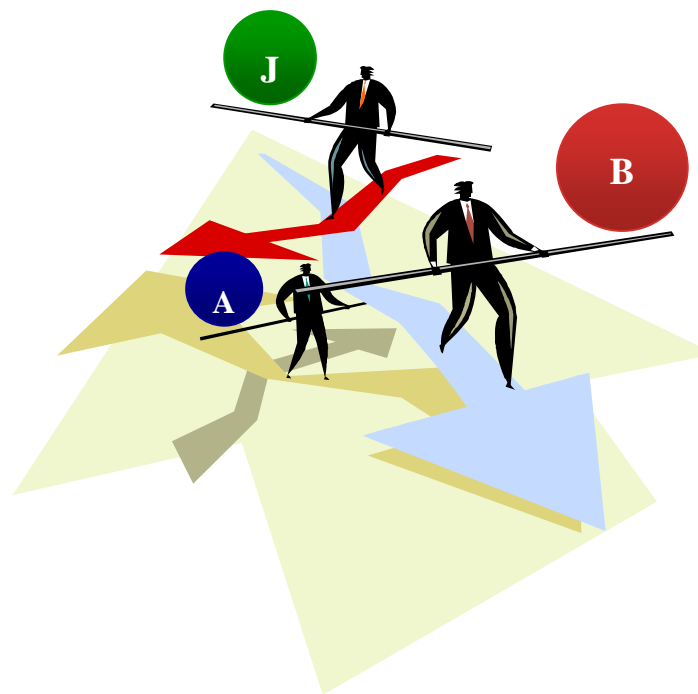
- Sharing risks & benefits of research in a fair way, between all parties, e.g. sponsors, trial participants & communities.
- It is fair to:
 - invite people to participate to help researchers reach the scientific goals of the research, not because it is convenient to ask them.
 - select participants in a way that lowers the risks, e.g. choosing those less vulnerable.
 - ask a person to take risks, if he or she or the population they represent might benefit from the research.
 - ask those who may benefit to take on research risks & burdens.





Balancing ethical principles

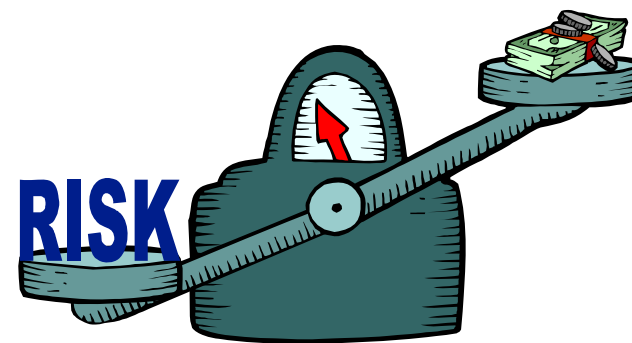
- In cases where ethical principles are in conflict with each other:
 - researchers need to try to balance them & to make a decision about how to move forward.
- See case study – *A Balancing Act.*





Undue inducement

- The incentive is too large.
- So volunteers are influenced & cannot make a free choice.
- They agree to take on risks they would not normally take.





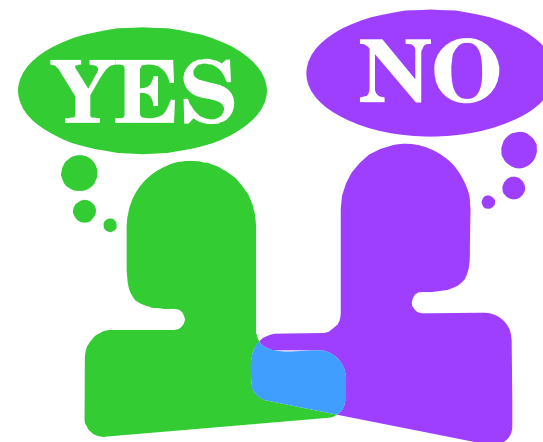
Basic requirements for ethical research

- a) Must be socially valuable for the country & scientifically sound.
- b) Selection of trial participants must be fair.
- c) Risks to individuals must be outweighed by the benefits to individuals and/ society.
- d) Independent ethical review.
- e) True informed consent.
- f) Full & meaningful community involvement and participation.
- g) Ongoing respect for volunteers & trial participants.



Informed consent

- Based on respect for autonomy.
- Refers to a person's right to decide whether or not they will participate in the research.
- To give informed consent, a person must:
 - have & understand all the relevant information, and
 - must decide to consent without undue pressure, control or influence from others.





What should informed consent include?

- **Information:** enough information & time to think about the information to make a good decision.
- **Understanding:** Information should be put in a way that volunteers can understand.
- **Freedom:** Volunteers must not be forced, threatened, punished or put under undue influence to make a decision. They must choose freely.
- **Capacity:** Volunteers must have legal capacity to consent – recognised by the law as old enough & capable enough to make the decision.
- **Explicit (usually written) consent:** Volunteers must show they agree to participate fully or clearly, e.g. by signing a written informed consent form.

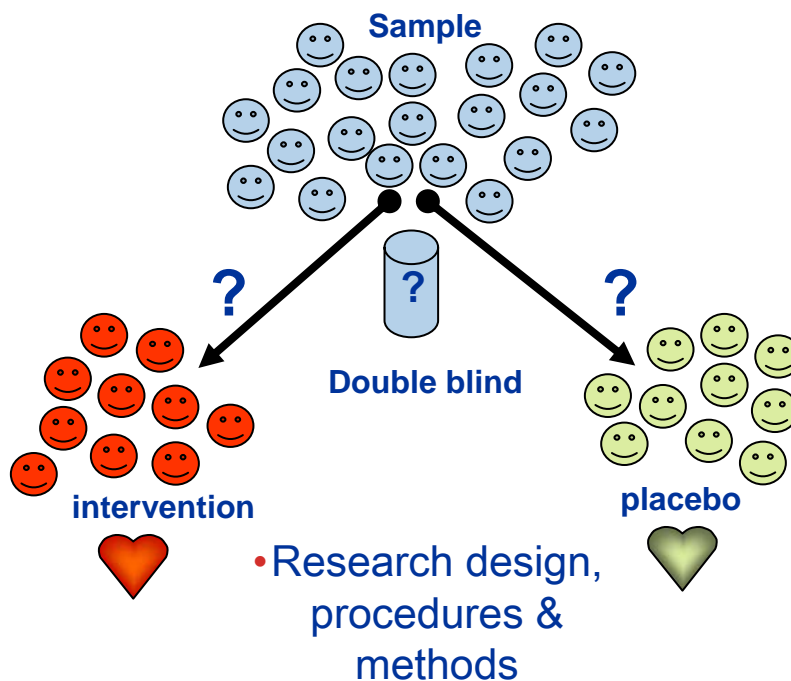
If they cannot or do not want to sign, other ways must be found to record their consent.



- the trial & why it's in the area
- the vaccine



of participation



- Personal impacts e.g. stress of regular HIV tests



- Freedom to withdraw at any time