WHAT IS INFORMED CONSENT AND WHO ACTUALLY OWNS THE DATA?

Ms Malebo Malope

Genetic Counsellor/ Lecturer

Medical Genetics and Genetic Counselling Unit

Division of Molecular Biology and Human Genetics

Stellenbosch University, South Africa

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Bioethical principles

- Autonomy
- Non-maleficence- do no harm
- Justice
- Beneficence

INFORMED CONSENT

Tuskegee Experiment - https://www.cdc.gov/tuskegee/timeline.htm

- Definitions
  - **Informed:** "having a lot of knowledge or information about something" - https://dictionary.cambridge.org/dictionary/english/informed
  - **Consent:** "permission for something to happen or agreement to do something"- Oxford languages
  - **Autonomy:** "is the capacity to make an informed, uncoerced decision"- https://en.wikipedia.org/wiki/Autonomy
  - Autonomy relies on one being **fully** informed
  - Research integrity

GUIDELINES: INFORMED CONSENT

It has long been part of South African law that a patient must provide informed consent for all medical treatment (diagnostic or therapeutic) on him/her (*Stoffberg v Elliot*, 1912). Basically, informed consent means that sufficient information is provided to the patient to make an informed decision and that the patient actually understands the information and the implications of acting on that information. Informed consent relates to a person's right to human dignity and autonomy. The medical practitioner has the duty to obtain the consent, as s/he is in a position to answer questions and provide further details.

According to the HPCSA Guidelines for Good Practice in the Health care professions, there are general and ethical guidelines which must be adhered to for a practitioner to be practicing within the ethical and legal boundaries which is required not only by law, but also by moral code.

https://www.avac.org/principles-research-ethics#:~:text=The%20term%20autonomous%20means%20that,whether%20to%20participate%20in%20research.
https://www.samedical.org/images/attachments/guideline-on-informed-consent-jul012.pdf

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Consent process

- All aims, objectives and methods
- Sample and data manage – who has access and how will it be stored& managed
- Benefits and harms and loss/ data breach of sample/ data
- Umbrella/ big study- continuous consent, go back to participant
- Ability to withdraw from the study

Considerations

- Use of language- literacy , lay mans terms
- Language the participant understands clearly- translate consent formed, use of interpreter or research assist who speaks the language
- Answer participant's questions
- Voluntary consent vs consenting under duress
- NB cultural and language barriers

Other considerations

- Continuous consent
- Samples from minors and reconsent when hey are autonomous adults
- Update participants when there is a new project manager/ contact person
- Alternative contact details of the participants

DATA OWNERSHIP

Who owns the data?

- The participant- valuable possessions
- The researcher- safety deposit box
- Institution – the bank

Sample (DNA)

- Belongs to the participant
- Their DNA
- Your role is to use it responsibility – the bank would not let just anyone access the safety deposit box

Data management

- Only for intended use –can't recycle to another project not consented for
- Transparency on management
- Protection of personal information Act, 2013
- Shared database with collaborators

Withdrawal from the study

- Then what?
- Has the data been disseminated publicly yet?
- Can you continue to use the data?

Checklist

- ✓ Was the study information provided in a language the participant understands?
- ✓ Were all the aims, objectives, methods, data storage and data dissemination explained to the participant and did you ensure that they understand?
- ✓ Were contact details provided to the participant?
- ✓ If verbal consent, did you provide them with a copy of the information sheet?
- ✓ Did you explain circumstances in which they may withdraw from the study and who can be contacted?
- ✓ Did you discuss privacy & confidentiality ?
- ✓ Did you explain how the data will be de-identified and stored ?
- ✓ If for umbrella/large studies did you explain how long their data or sample will be stored and if further consent for future studies will be required?

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THANK YOU-

CONTACT: MMALOPE@SUN.AC.ZA