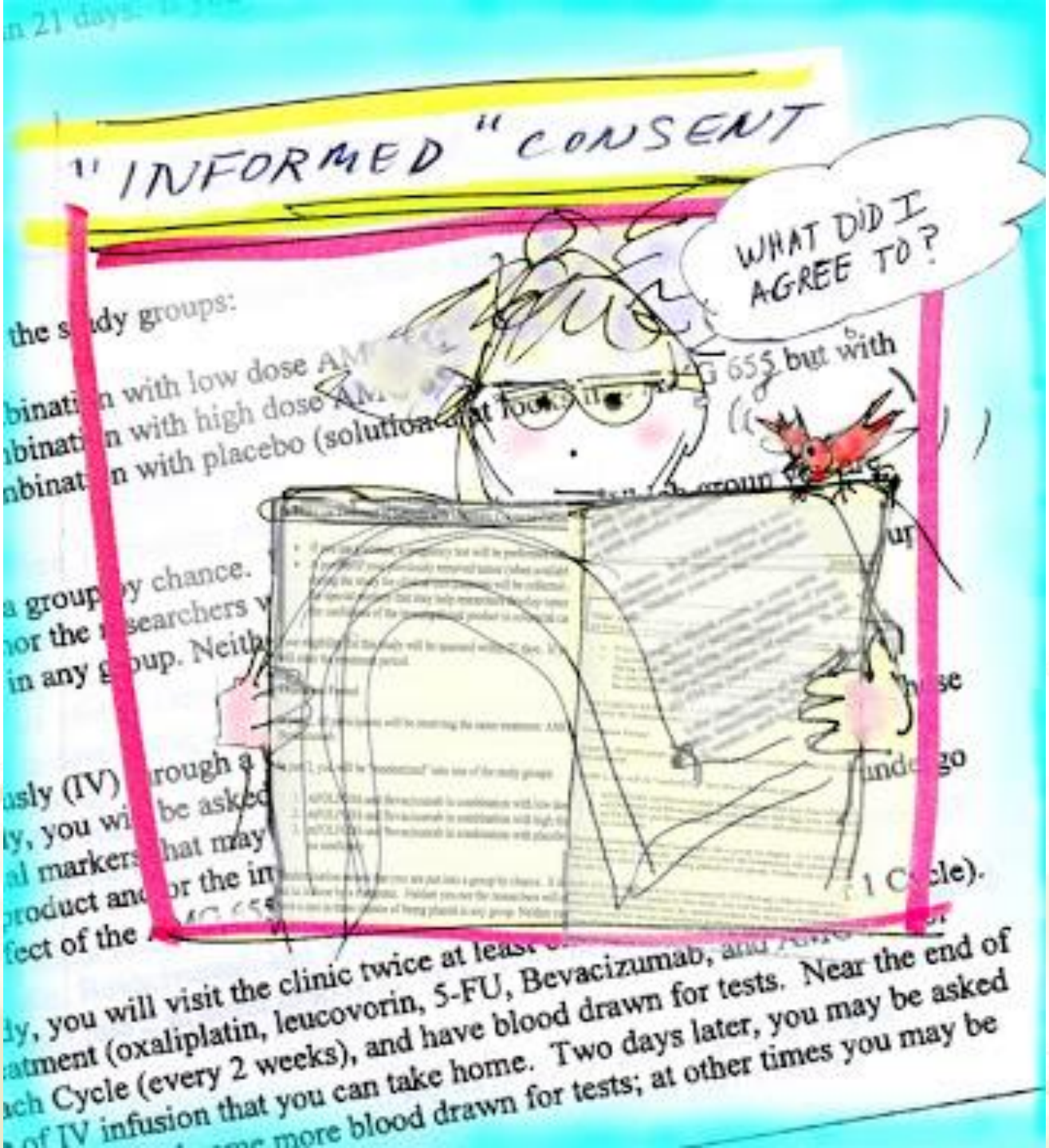
Consent for Data Sharing in H3Africa Genomics Research

Jantina de Vries



Cartoon by Amy Marash

Autonomy

- ‘Deliberated self-rule’
- The moral commitment to treat others as ends in themselves and never merely as means;
- Two ways of ensuring autonomy:
  - **Privacy** and **confidentiality**: not to disclose patient or participant data
  - **Consent**: to consult with patients/ participants about procedures and get agreement

Valid consent

- **Valid consent** needs to be:
  1. Information needs to be comprehensible (*understandable* and *sufficient)*
  2. Given *voluntarily*
  3. By a *competent* adult
- So three components of valid informed consent are comprehensibility, voluntariness and capacity to consent.

- In SA, the Constitution says that "everyone has the right to freedom and security of the person, including the right: not to be subjected to medical or scientific experiments without their informed consent" (12th Provision of the Constitution, 1996).

Guidelines for IC

- Many national & international guidelines exist for IC, e.g. CIOMS, Nuffield, WMA
- Range from giving 'general guidance' to detailing > 25 types of information to be provided. Necessary information is:
  - purpose of the study;
  - research procedures involved;
  - the duration of participation;
  - potential risks & benefits;
  - right to withdraw;
  - confidentiality .

H3Africa Guidelines Informed Consent

- Developed by the H3A WG Ethics
- Available via the H3Africa website

Comprehension

1. Is the information clear?
2. Is the information appropriate (for the participants)?
3. Is the means of conveying information appropriate?

"Urine will be obtained for routine tests. Urinalysis will be performed on site and will be assessed for the presence of blood, protein, glucose, ketones, nitrates, leukocyte esterase, uro-bilinogen and bilirubin. This will be done for safety reasons"

Capacity

1. Who may have reduced capacity to decide?
   a. People who are not of ‘sound mind’: e.g. patients with dementia, psychiatric conditions
   b. Young children
   c. Intellectually compromised people
   d. Some physically compromised people (e.g. those in a coma).
2. Is this a fixed characteristic of people, or not always?
3. Who decides?
   a. E.g. anorexia patient: may be of sound mind, but make irrational choices.

Voluntariness

- Means that decisions are made freely, without pressure or inducement
- Many factors could reduce voluntariness, for instance
  - Access to healthcare provided by the project
  - Money or goods given for participation (also called ‘inducements’)
  - Status of healthcare professionals (see photo)

Genomics and Consent

- Difficulty of terms used, e.g. genes, genome, DNA, data sharing etc
- Enrolling healthy participants as well as patients
- Sharing of data
  - Open-ended nature of research
  - Possibility of re-use
- Explaining genomics: reference to inheritance

Genomics and data sharing

- Confidentiality
  - Requires that study information and data is kept secure
  - Often requires *de-identifcation, anonymisation,* other terms*?*
- Right term is ‘de-identified’ or de-linked data

Genomics data

- Challenge with genomics data is that it is always unique to the individual
- Not possible to really ‘de-identify’?

➢ How to deal with this in informed consent?

  - Not talk about it?
  - Discuss it, but how?
    - Fingerprint analogy

Data sharing and consent

- Agreement is that consent forms need to include section on data sharing

"Your blood samples will be stored in a locked freezer in our laboratory and your personal information on a secure computer. But your genomic information is unique to you, and also tells us something about your family. It is always possible that someone may find out that you participated in this project. However, it is very unlikely that this will happen and we will do our very best to ensure that it will not."

H3Africa Guidelines Informed Consent

Acknowledgements

- Informed Consent cartoon slide 2: Amy Marash, http://cancerissofunny.blogspot.com/2010/10/double-blind.html (accessed 29 May 2014)