Informed Consent Process and Confidentiality

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INFORMED CONSENT

- What is informed consent?
- Why do we need informed consent? Historical
- From who do we request informed consent?
- How do we get it?
- How can we be sure we're doing it right?

Informed consent

- What it is:
  - A continuous process
  - Acknowledging respect for persons (Autonomy)
- What it is NOT:
  - A legal document
  - A risk management tool for an investigator or an institution
  - A formality

Goal of consent process

"To provide participants (people) with sufficient information about the study so as to empower them to make informed choices about whether to begin or continue participation in clinical research."

Historical events

- Nazi war crimes → Nuremberg code (1949)
- Human radiation experiments, etc. → Declaration of Helsinki (1964)
- Tuskegee Syphilis study → National Commission Belmont Report (1977)

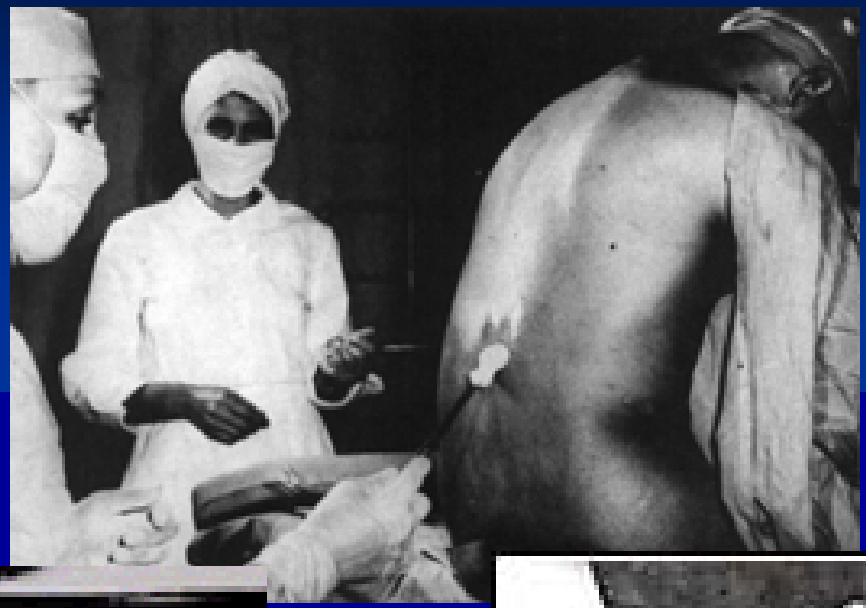
Nuremberg, Germany
December 9, 1946 to August 20, 1947

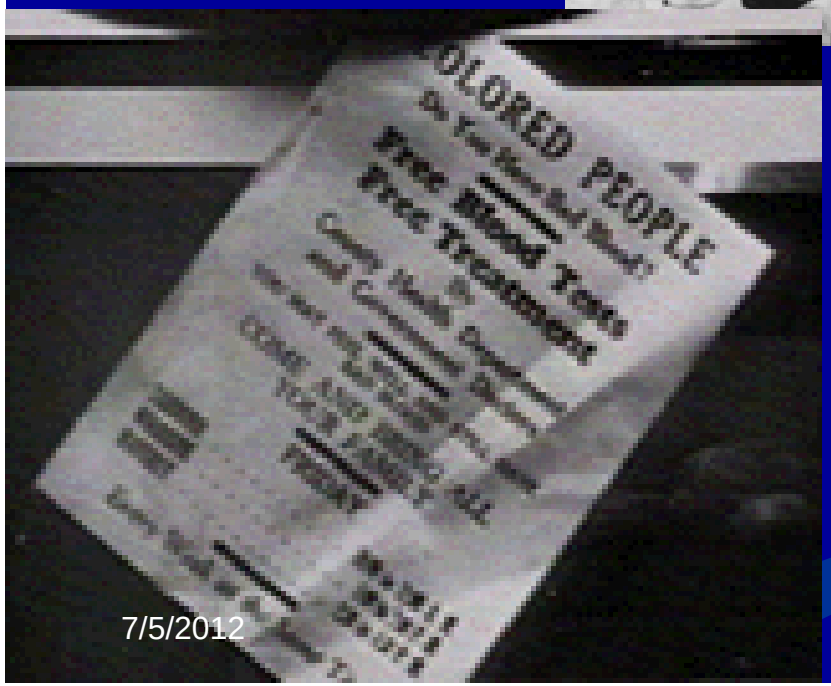
- Required voluntary consent prior to participation
- Investigator responsibility to obtain consent
- Information gained by using human subjects would be unprocurable any other way

Declaration of Helsinki (World Medical Association - 1964)

- Articulated ethical principles for use by physicians conducting human research
- Affirmed the autonomy of the individuals
- Universally adopted to ensure the rights and welfare of human subjects of research

Tuskegee Syphilis Study





(Courtesy National Archives)

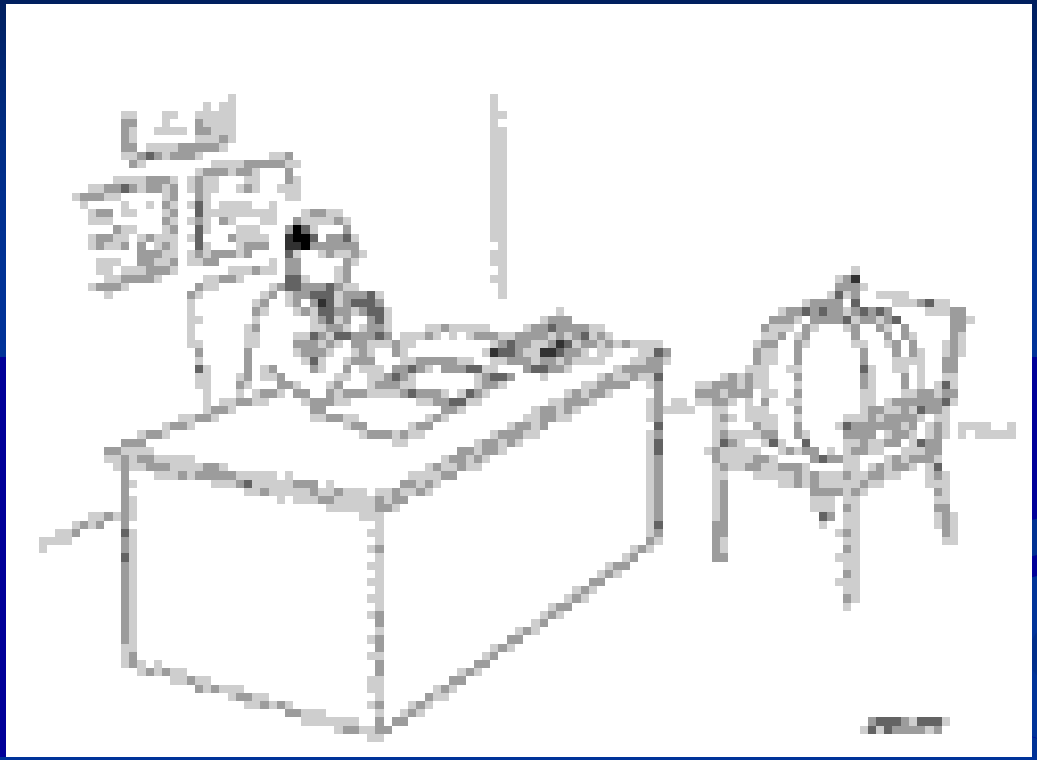
Post- Tuskegee events

- National Research Act 1974
- National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
- Belmont Report
  - Defined the 3 basic principles that should govern all research involving human subjects
    - ***Respect for persons***
    - ***Beneficence*** (maximize benefits, minimize risks, avoid harm)
    - ***Justice*** (benefits and burdens equally distributed)

So, Why do we need the consent?

- Demonstrate that researchers have:
  - Respect for persons
  - Respect for autonomy of decision making

Informed consent; what is it?



“It’s a very simple procedure. We slice off the top of your head, scoop out your innards with a spoon, and carve out your eyes and mouth.”

Informed consent as a process

"…involves a dynamic and continuing exchange of information between the research team and participants throughout the research experience…"

Informed consent process

- **Threshold**
  - Decision-making
  - Voluntariness
- **Information**
  - Disclosure
  - Understanding

Informed consent process

- **Authorization**
  - Indication for agreement

  - Consent Form
    - Consistent with disclosure
    - Readable

How do we get informed consent?

- Varies according to study design and nature of participation
  - Verbal (more common in clinical practice)
  - Written Form (commonly used in research) **Consent Form**
    - Witnessed consent (written)

What is a Consent Form?

- "…a starting point for the necessary exchange of information between investigator and potential participant."
- "…the foundation not the entirety…"

Elements of an Informed Consent

- Disclosure on:
  - Purpose
  - Expected duration
  - Procedures
  - Identification of experimental procedures
  - Approximate sample size
- Voluntariness
- Risks
- Benefits
- Alternatives
- Confidentiality
- Compensations
- Who to contact

How can we do it correctly?

- **Capacity**
  - **Understand** nature and ramifications
- **Voluntariness:**
  - Freely coming to a decision
  - Free from coercion or undue influence
  - Assumes capacity
- **Respect vulnerable persons**
  - unable to consent

Ethical issues related to consent

- **Capacity and decision making**
  - **Who has capacity to decide and how to determine so?**
  - **Substitute decision makers?**
- **Disclosure and Voluntariness**
  - **What information?**
  - **How much of it?**
  - **When to give the information?**

Ethical issues related to implementation

- **Voluntariness**
  - How to determine voluntariness?
- **Protocol adherence**
  - Do we follow the protocol?
  - How do we changes/amend protocols?

Ethical issues

- **Vulnerable groups**
  - **Identification of vulnerable groups**
  - **Conditions for carrying out trials or research in vulnerable groups**

Can research be done on vulnerable people?

- As long as:
  - Proposal has been critically reviewed
  - It does not pose risk or minimal risk to subjects
  - Cannot be carried out in capable subjects to consent
  - Must have maximum benefits to others in same category as the subjects

Are we doing it right?

- Behaviors during informed consent (>1000 patients taking a survey)
  - 41% did not read
    - 57% who read spent < 60 seconds
  - 22% asked questions
  - 44% did not accept the form

Why do people participate in biomedical research?

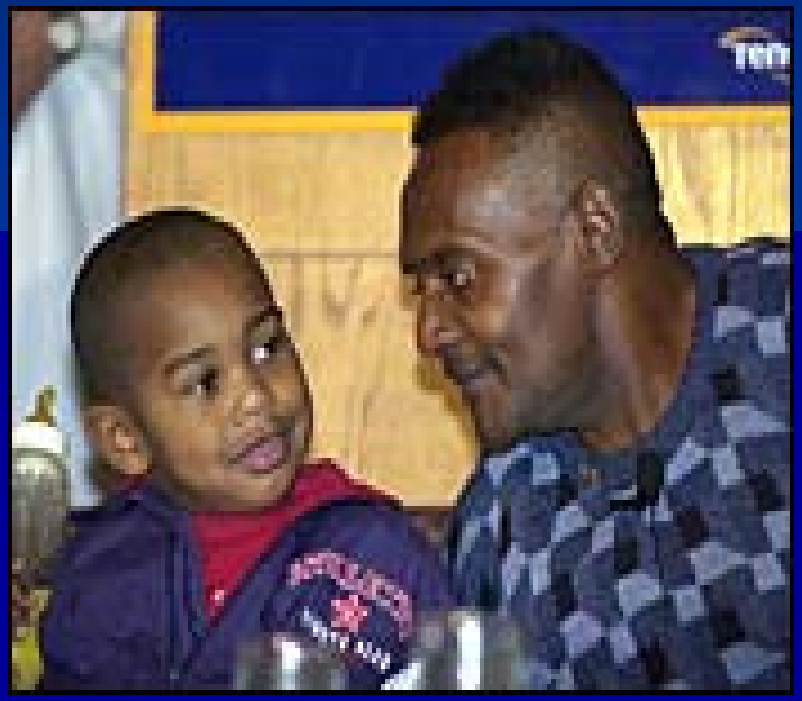
- Altruism
- Free medical care and medications
- Trust
- Self-interest
- Attention
- Do we want to constrain people if they are doing things for the wrong reasons?

James “Butch" Quinn: Artificial Heart Recipient

- 52 year old who received the Abiomed heart
- Lived for 10 months with the device
- Sustained fatal stroke

- **Reaction: Lawsuit over consent**
  - Recipient's widow says she and her husband were misinformed and misled on risks, benefits and the potential for pain and suffering .

James “Butch" Quinn: Artificial Heart Recipient



- “There was no quality of life. It was too painful. He said he wished he'd never done it."

What was wrong with the consent process?

- 13-pages detailing "significant risks"
  - stroke, brain and organ damage, discomfort and pain.
- “New and experimental operation”
- Complications could occur (previously unknown or unforeseen)
- Potential benefits “uncertain and not proven”

Confidentiality

- **"Privacy is a basic right permitting individuals to decide the manner, and extent to which information concerning them should be shared with others"**
- **"Is central in the researcher-participant relationship, and is based on trust"**
- **"Breach of confidentiality threatens the relationship"**

Guidelines on ethics for health research in Tanzania, 2nd Ed, 2009

Essentials of confidentiality

- Information presented during the study is **private** and **confidential**
- Investigator has **professional** and **legal duty** to safeguard information
- Investigator must be **aware of consequences** of breach of confidentiality

What to do to safeguard confidentiality?

- Keep record safely secured
- Keep records in a form that has no identifiers
- Where disclosure may result in identification of person(s), concerned or legally authorized persons MUST be made aware
- Where person(s) have been identified, they should be made aware that they are at liberty to withhold their consent to disclosure at any time
- All research involving access to personal records MUST have approval of IRB

Ethical dilemmas of confidentiality

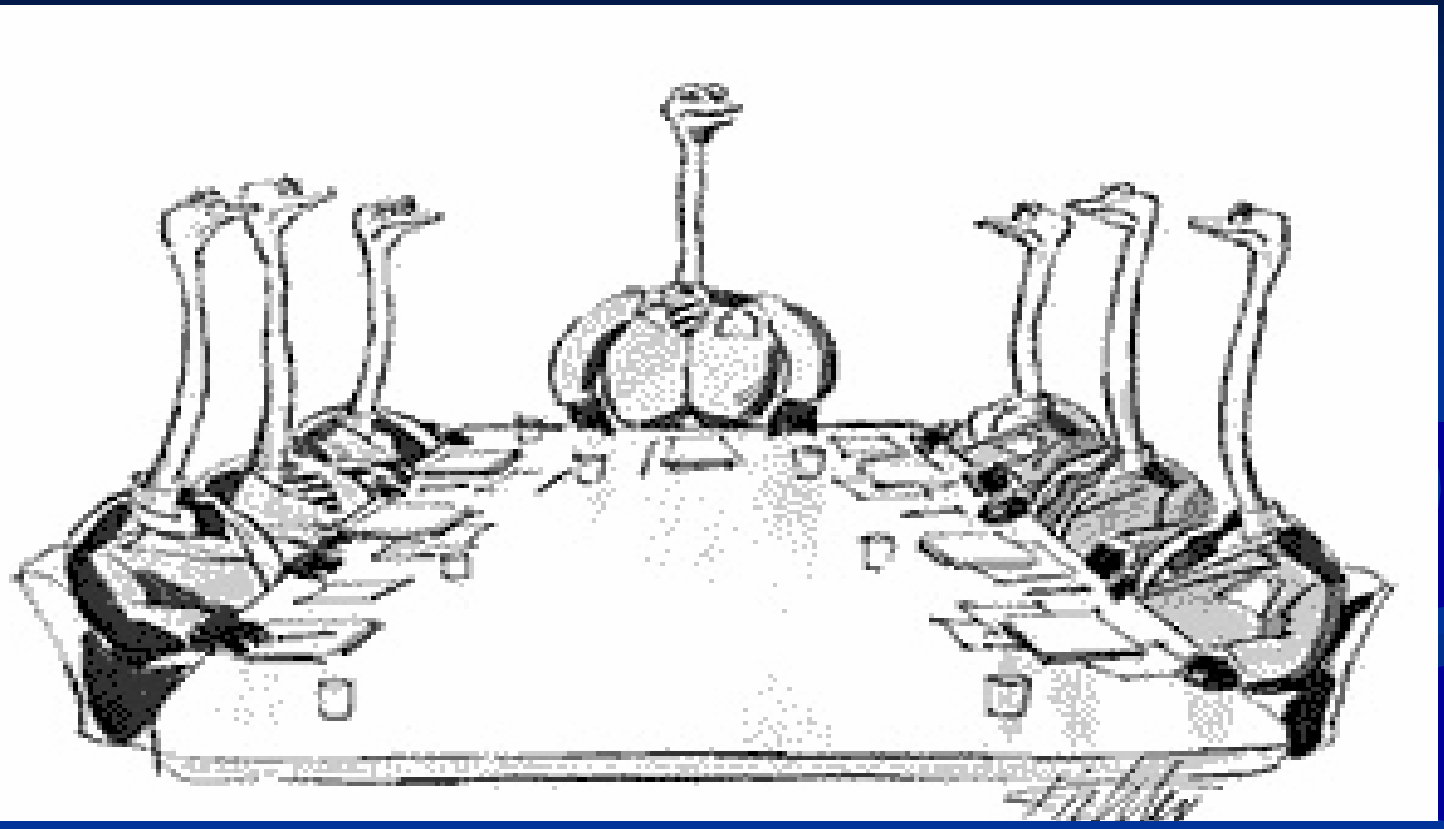
- Couple, one is HIV sero-positive the spouse is not aware
- Inhuman practices by a fellow professional to prisoners
- A school child on drugs and pleads not to inform the school and parent
- Concern that high level care during research may have constituted undue incentives
- Disguised use of client material for teaching purposes

Ethical dilemmas of confidentiality

- Suspected child abuse, elder abuse, or dependent adult abuse
- When threat to injure or kill oneself is communicated
- Situations where serious threat to a reasonably well-identified victim is communicated
- Participant signs release for records if involved in litigation
- Do participants under 18 years have full confidentiality from their parents?

Role of IRB

- Ethical standards in research are maintained
- Rights and autonomy of participants are preserved
- Participants and researchers are protected from harm and any form of exploitation
- Assure public that research is conducted in an acceptable manner
- Assure public that research is conducted in the best interest of the community



“A motion has been made and seconded that we stick our heads OUT of the sand.”

THANKS