Principles of Informed Consent and Informed Refusal

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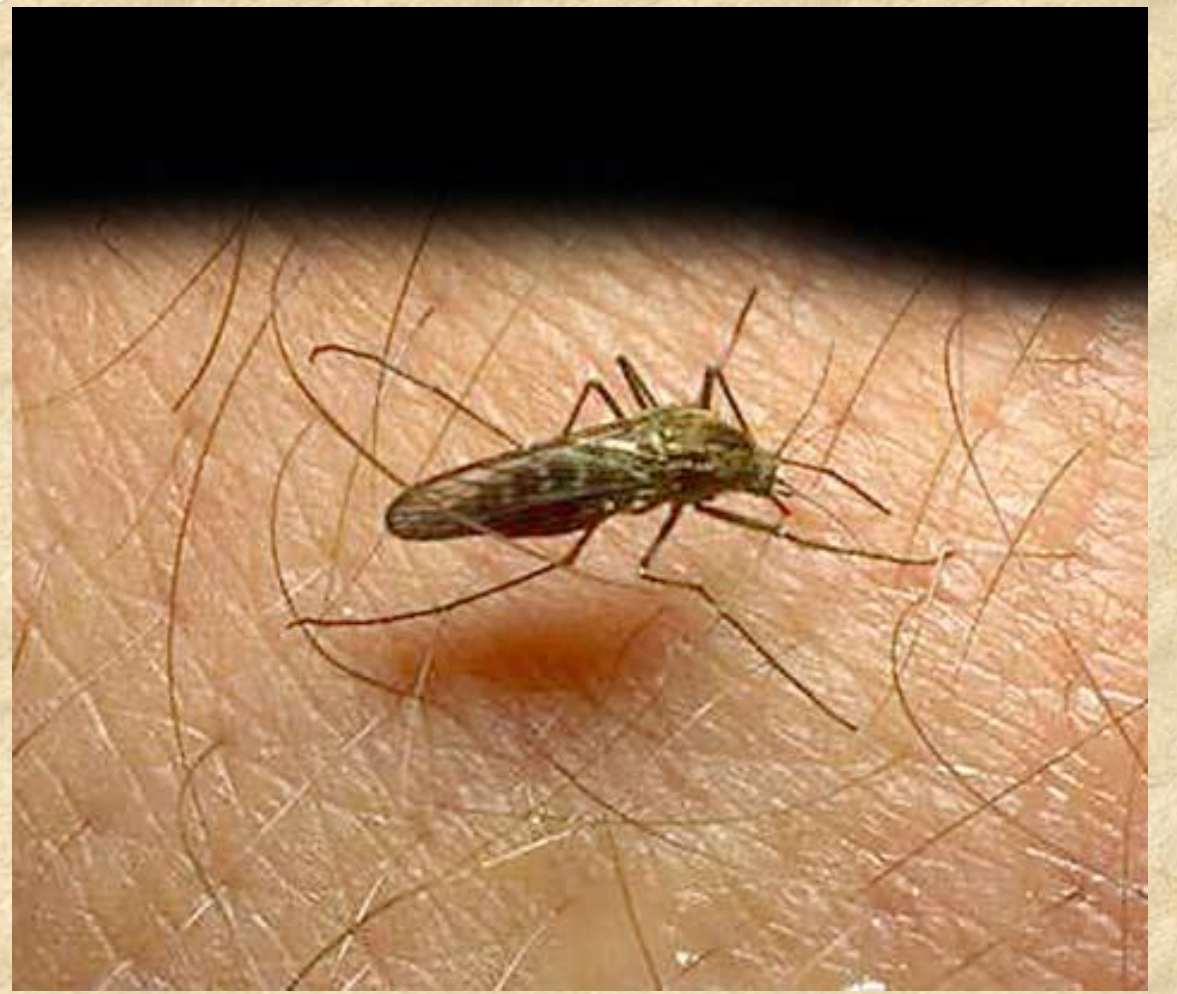
Informed Consent

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body …"

Schloendorff v. Society of New York Hospital,
105 N.E. 92, 1914

1944 Malaria Study at Stateville Penitentiary

- Conducted human trials in Illinois penitentiary
- Prisoners inoculated with malarial mosquitoes
- Praised in *Life Magazine* as heroes



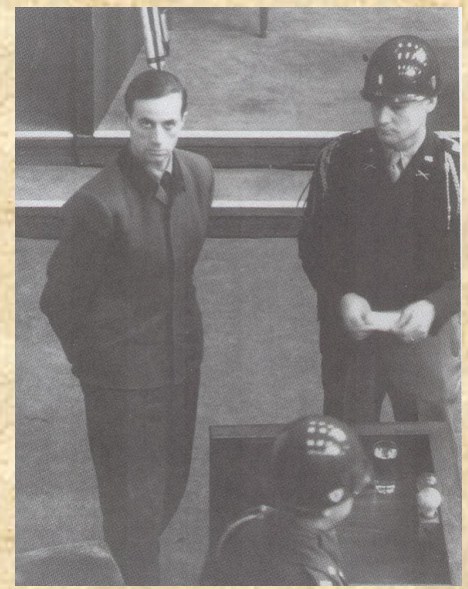
1946 Nuremberg Trials

Nazis prosecuted for medical experiments on prisoners during WWII

15 of 23 defendants found guilty

7 sentenced to hanging

5 sentenced to life imprisonment



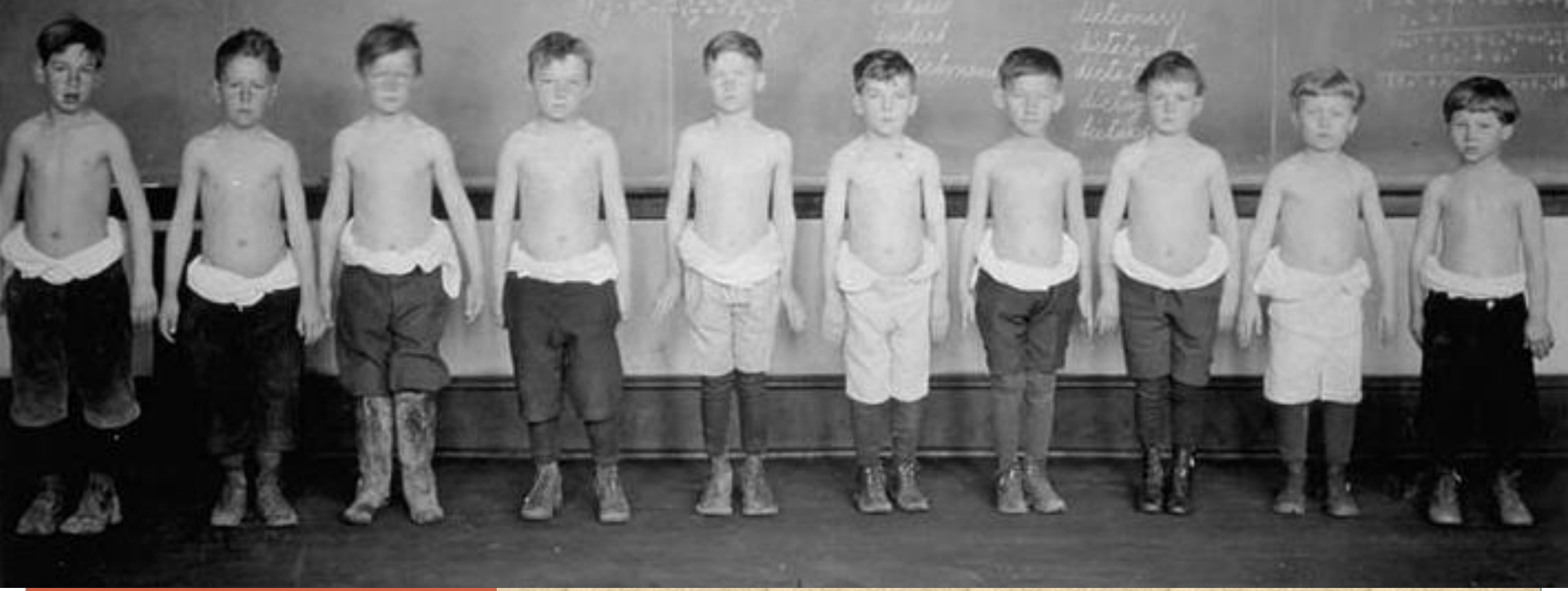
1946-1953 Fernald School

- MIT researchers worked with school staff to conduct experiments on children
- Non-therapeutic nutrition experiments involving low dose radiation
- Parents not informed

1946-1953 Fernald School

Letter to Parents May 1953

"We have asked for volunteers to give a sample of blood once a month for three months, and your son has agreed to volunteer because the boys who belong to the Science Club have many additional privileges."



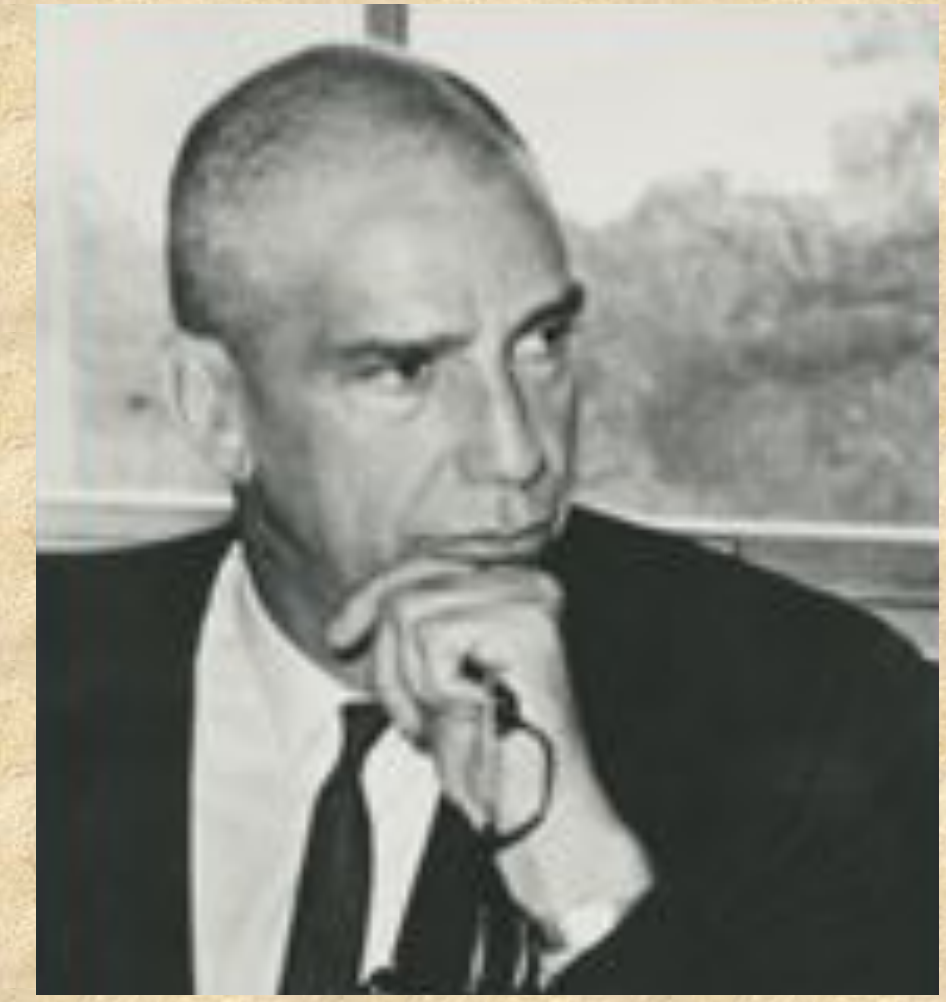
The Science Club

The Fernald School, 1954

1954-1963 Sloan Kettering Cancer Study at Jewish Chronic Disease Hospital

- Study conducted on 22 terminally ill patients
- Given infusion of cancer cells without their knowledge or consent
- Study was to determine if cancer patients lacked immune response to other types of cancer cells
- Matched with healthy controls (prisoners)

1954-1963 Sloan Kettering Cancer Study at Jewish Chronic Disease Hospital



Interview with Dr. Southam (1964):

"The reason we did not tell them was for their sake, not ours. The cancer patients at Memorial Hospital seem to develop a bizarre, defensive reaction against the knowledge they have cancer…"

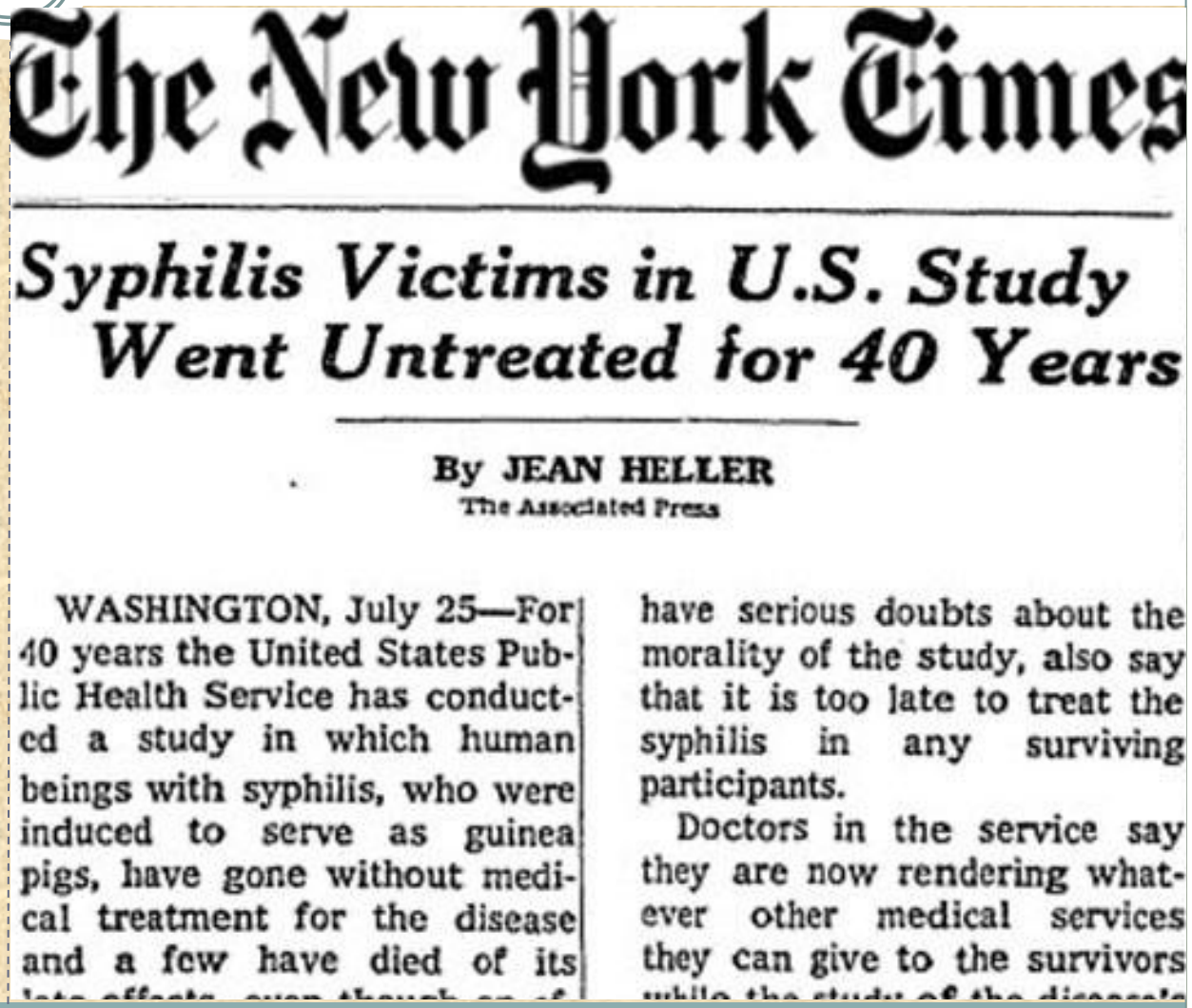
1932-1972 Tuskegee Syphilis Study

- 40-year study of “untreated syphilis in the male Negro”
- Study was exposed in 1972
- Public outcry and government commission

1932-1972 Tuskegee Syphilis Study

Lesson of Tuskegee Syphilis Study:

- Violated basic ethical principles:
  - Involved deception and failure to obtain consent
  - (Potentially) exposed patients to harm
  - Research conducted on a vulnerable population
- Raises issues of race and gender as well



The New York Times

Syphilis Victims in U.S. Study Went Untreated for 40 Years

By JEAN HELLER
The Associated Press

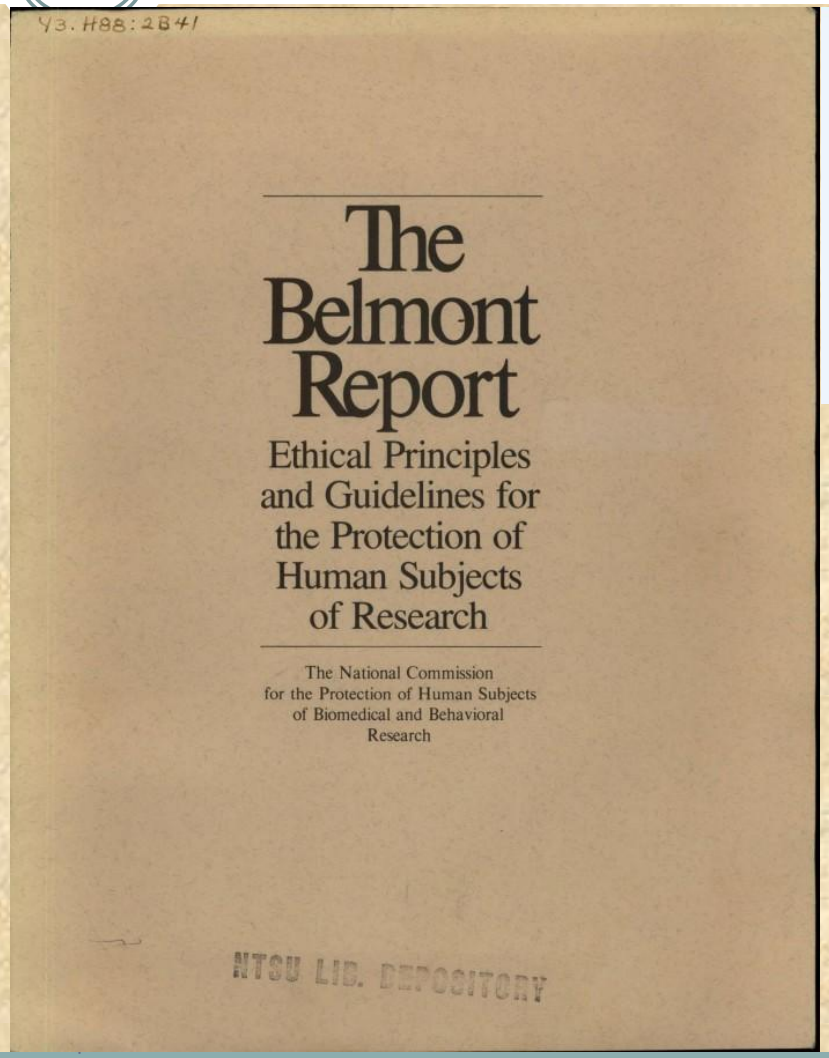
WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were induced to serve as guinea pigs, have gone without medical treatment for the disease and a few have died of its

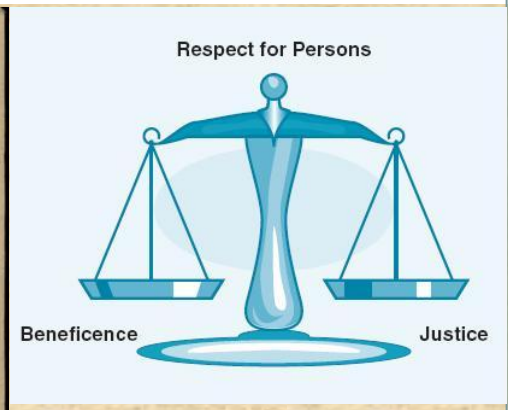
have serious doubts about the morality of the study, also say that it is too late to treat the syphilis in any surviving participants.

Doctors in the service say they are now rendering whatever other medical services they can give to the survivors

1974 The Belmont Report

- Three guiding principles:
  - **Respect for Autonomy**
    - Protect patient's right to informed consent
  - **Beneficience / Nonmalficence**
    - Physician has a duty to help and not harm the patient
  - **Justice**
    - Burden of risks and benefits should not fall disproportionately on the most vulnerable





Which of the following is an example of Implied Consent?

A. **Treatment provided in emergency situation to prevent death**

B. **Patient standing in line to receive an Influenza vaccine**

C. **Surgeon finding a tumor during operation and proceeding in its removal**

D. **Providing treatment based on what the patient's spouse wishes**

E. **Providing information based on what the police have requested**

Implied Consent for Simple Procedures

- **Implied consent** for "simple" procedures is obtained when:
  - Patient agrees to have blood drawn
  - Patient takes the medication
  - Patient agrees to go to radiology for the x-ray

- Documentation for simple or implied consent:
  - General authorization given in the conditions of admission

"Implied" vs. "Informed Consent"

- **No consent** = Battery (Intentional tort)
  - E.g., wrong surgery or exceeds scope of consent
    - *Perry v. Shaw (2001) 88 Cal App 4th 658*
- **Implied Consent:** Conditions of Admissions
  - Applies to simple, common procedures with remote risks, e.g., blood draw
  - Signed Conditions of Admission sufficient for administration of Ativan and echocardiogram
    - *Piedra v. Dugan (2004) 123 Cal App 4th 1483*
- **Informed:** Additional process required
  - *Cobbs v. Grant (1972) 8 Cal 3d 22*

When Informed Consent is Required

- **Informed consent** is shorthand for:
  - a process that involves giving the patient information so the patient can make an informed decision – to accept or reject treatment

- Informed consent is required:
  - When the procedure involves material risks that are not commonly understood
  - When required by statute

Basic Principles of Informed Consent

- Patients have the right to:
  - Know their health status, diagnosis, prognosis
  - Be involved in care planning, treatment and discharge planning
  - Receive information needed to allow them to make informed decisions
  - Decide when to accept and when to reject recommended care

Informed consent discussion must include the following EXCEPT:

A. **Risks and benefits of treatment**

B. **Alternatives to treatment**

C. **Diagnosis**

D. **Family's wishes**

E. **Risks of not receiving treatment**

Informed Consent Discussion

- **Informed consent** discussion needs to include:
  - Nature and purpose of procedure
  - Likelihood of benefits, risks, complications and side effects of procedure and its alternatives
  - Possible alternative methods of treatment
  - Potential problems during recuperation

Informed Consent Content

- What information is sufficient?
  - Information the MD should know would be considered significant by a reasonable person in the patient's position
  - Supplemented by patient's unique concerns/condition (as known or should be known by the physician)
    - *Truman v. Thomas (1980) 27 Cal 3d 285*

Informed Consent Content

- At a minimum, a physician must disclose a known risk of death or serious bodily harm and explain the complications that can occur; and
- Any additional information a skilled practitioner of good standing would provide under similar circumstances
  - Arato v. Avedon (1993) 5 Cal 4th

Informed Consent Content

- No obligation to inform a patient about a test or treatment if neither is recommended
- No duty to advise patient of unapproved treatment
  - *Schiff v. Prados (2001) 92 Cal. App 4th 692*
- No duty to divulge a "small or remote" risk
  - *Scalere v. Stenson (1989) 211 Cal. App 3d 1446*

Role of the Physician

- **Physicians** have the responsibility to give the patient information so the patient can decide
- When two or more physicians are involved, either they can divide the responsibility, or the hospital policy can allocate responsibility
  - Surgeon and anesthesiologist
  - Internist and radiologist

Documenting Informed Consent

- **Informed consent** is a process that includes:
  - A discussion with the patient/family by the physician performing the procedure
  - Documentation of the decision to consent to treatment or refuse treatment
    - Physician documentation: e.g., progress note evidencing discussion of risks, benefits and alternatives
    - Hospital documentation: completion of consent form

Changed Circumstances

- If the patient's health has taken a turn for the worse since surgery was originally contemplated, the patient and doctor should discuss the planned procedure in light of any changes in the benefits or risks, or alternatives

- Document! Without documentation, it is almost impossible to prove that further discussion happened

In which of the following cases is informed consent NOT needed?

A. **When immediate treatment is necessary to prevent death or permanent impairment**

B. **When a child is recognized as emancipated**

C. **When a patient is found to be incompetent**

D. **When a child is under care of the state**

Exceptions and Special Circumstances

- Emergency Exception
  - Impracticable to obtain consent and
  - Patient mentally incapacitated and
  - No authorized representative who can consent
  - Hospitals must make reasonable efforts to contact patient representative (California Probate Code Section 4716)
  - If prior refusal, and emergency subsequently results, the emergency exception may not apply
- Patient request for non-disclosure of information

Competency vs. Capacity

14-year-old girl presents to the emergency department, accompanied by her 10-month-old daughter and boyfriend. The boyfriend is the child's father. Patient complains of severe abdominal pain, she's febrile, and has a high white count. Plan is to take the girl to the operating room to perform an appendectomy. In this case, from whom should informed consent be obtained?

A. **Patient**
B. **Patient's parents** ✓
C. **Patient's boyfriend**

Competency vs. Capacity

Competence

- Competence generally considered a legal category
- Only courts can declare a person to be legally incompetent and take away the person's power to make decisions
- Courts can declare a person competent to make health care decisions, but not financial ones

What information must a patient understand to have Capacity? (May provide more than one answer)

- ✓ **A. The nature and seriousness of their illness, disorder, or defect**
- ✓ **B. The nature of the medical treatment that has been recommended**
- ✓ **C. The benefits and risks of any medical intervention that is being recommended by the person's health care providers, and the consequences of lack of treatment**
- ✓ **D. The nature, risks, and benefit of any reasonable alternatives**

What is the difference between "Competency" and "Capacity"?

- **Capacity**
  - A person who has not been adjudicated incompetent by a court but lacks capacity to make health care decisions (to be determined by physician – CA Probate Code Section 4658))
  - The incapacity may be temporary (e.g., patient is unconscious or confused due to meds) or more long-lasting

Presumption of Capacity

- The presumption is that patients are capable of making health care decisions (i.e., has capacity)
- The fact the family or physician may disagree with a patient's choice does not render the patient incapable of making the decision
- Factors to consider: medication, emotional turmoil, pain, mental disorder
- Psychiatric confirmation is not required (capacity determined by treating physician), but can be helpful when there is doubt, e.g., the patient may be depressed about the medical news and the depression is interfering with the patient's capacity to make the decision

Documenting Capacity/Competency

- If the patient has been declared incompetent by a court, the court order should be obtained and included in the chart
- If the physician has determined a patient lacks capacity, document decision and any factors supporting the determination
- If the patient is unrepresented, document process for decision making to determine competence and capacity

When is it NOT OK for the patient to refuse treatment?

A. **Refusal based on religious belief despite risk of death**

B. **Given adequate understanding of information, refusal based on uncertainty regarding success**

C. **Single parent at risk of death without family to care for child**

D. **Concern regarding risks of procedure**

Informed Refusal

- An adult patient with capacity has the right to refuse any and all forms of medical treatment
- An adult does not have the right to deny life-sustaining treatment for his or her child

Informed Refusal

- A patient's refusal to accept or pursue medical treatment should be informed
- Physician has duty to advise patient of all material risks which a reasonable person would want to be informed before deciding not to undergo the procedure
- Document refusal of all medical tests and procedures
- Includes refusal to see a specialist

Missing Consent in the OR

The patient is in the OR and we just discovered there is no consent form on the chart!

New Finding During Surgery

In the middle of surgery, the doctor discovered an unexpected problem that he wants to fix now. Can he?

Pressure from Patient to Assume the Risk

Attorney patient with severe back pain reports to the hospital for surgery by orthopedic surgeon

- Anesthesiologist reviewed the case the night before and realized that the patient had not stopped a medication per guidelines and could be at risk for bleeding
  - Cardiology consult says ok to proceed
  - Anesthesiologist does not wish to proceed

Patient threatens lawsuit, agrees to sign "hold harmless, assumption of risk" and threatens to report the physician to the medical board for abandonment

- What should the hospital do?

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