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Taking Informed Consent from Vulnerable Subjects

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Who are vulnerable subjects?

- Vulnerable research participants are those persons who are relatively or absolutely incapable of protecting their own interests.
- The research team must be aware of the special problems surrounding research involving vulnerable populations.
- The proposed involvement of vulnerable populations requires detailed justification and additional safeguards to protect their welfare and safety.

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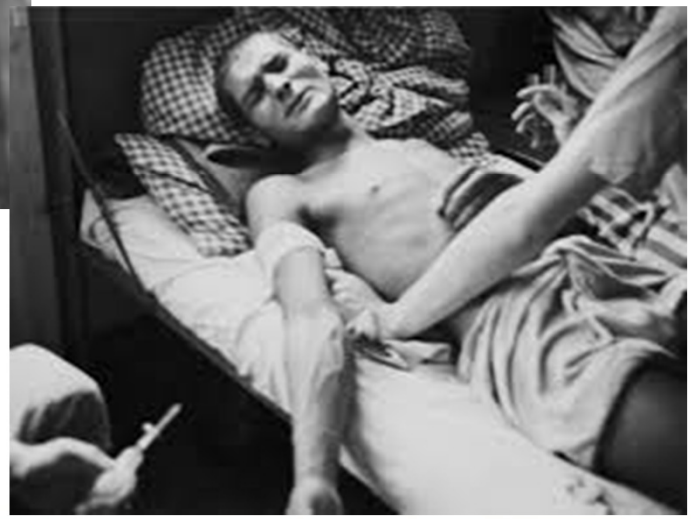
Nazi Human Experiments



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Tuskegee Trial

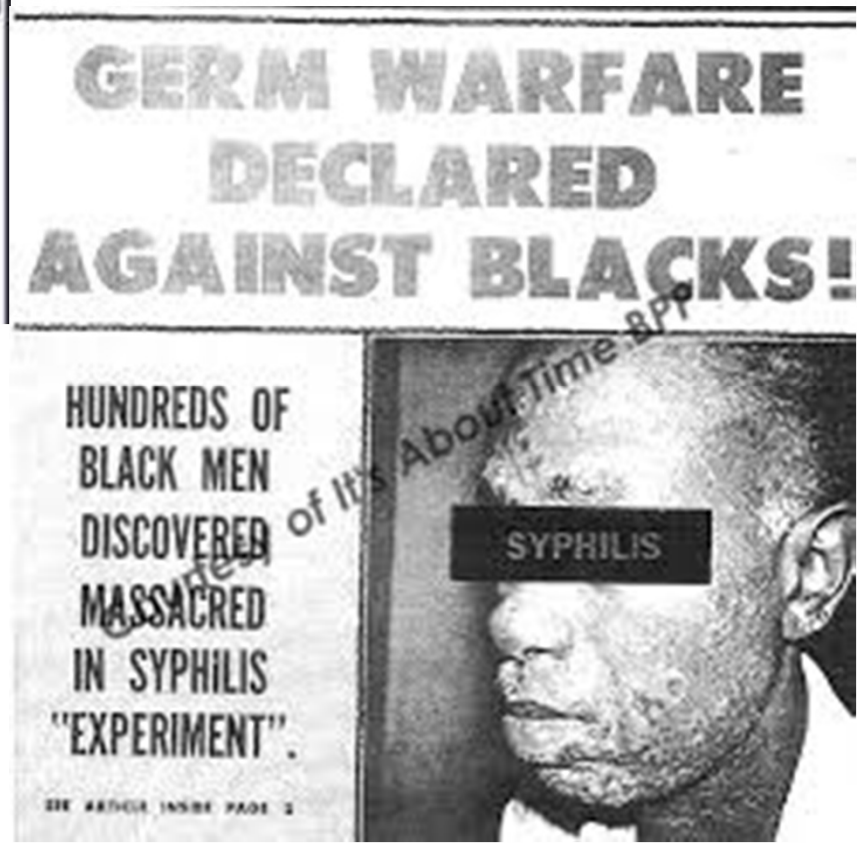
The New York Times

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

By JEAN HELLER

WASHINGTON, July 25—For 40 years the United States Public Health Service has conducted a study in which human beings with syphilis, who were

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



GERM WARFARE DECLARED AGAINST BLACKS!

HUNDREDS OF BLACK MEN DISCOVERED MASSACRED IN SYPHILIS "EXPERIMENT".

SEE ARTICLE INSIDE PAGE 2

SYPHILIS

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1. Children

- A child is a person less than 21 years of age
- Children cannot legally give consent.
- Any study involving children requires IRB review and approval.
- Parental consent must be obtained in all cases.
- In addition to the parent or guardian's written consent, research should not proceed without the child's written assent to participate.

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How about youths?

- Research looking at special issues in youths:
- Sexual behavior
- Smoking
- Emotional distress

- Would a young person participate in the study if we asked for parental consent?

- DSRB has in certain cases waived off the parental consent if:

✓ the study yields important information

✓ It can only be done in this population

✓ Getting parental consent may have impede the research.

- Researchers may discover sensitive information about subjects that is not research related e.g., sexual activity, STDs, use of illegal substances and child abuse.
- Investigators need to think about how they will handle such situations should they arise and indicate that in the protocol and/or in the consent form

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2. Questionable Capacity to Consent

- Capacity to consent means a person has sufficient mental capacity to understand the information provided, to appreciate how it is relevant to their circumstances, and to make a reasoned decision about participation in the study.
- Patients with dementia, mental illness, neurological conditions etc

Acutely Psychotic Patients

- A study looking at anti-NMDA antibodies in patients with first-episode psychosis

- Challenges:

✓ Acutely unwell

✓ Families distressed

- Informed consent was taken from LPA or NOK
- Time was given for them carefully consider the study procedures and risks involved
- Consent was taken from patient when he/she got better and had the capacity to do so.

- Special precautions:
  - Additional use of witnesses for consent
  - Use of patient advocates
  - Renewing consent at specific stages of the research
  - Limiting time period for approval

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An assessment of the understanding and motivations of patients with schizophrenia about participating in a clinical trial ☆

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ABSTRACT

Enrollment of an adequate number of subjects for a clinical trial is a perennial challenge and this might arguably be even more difficult and complex in trials involving patients with schizophrenia. In this paper, we used a modification of the Prospective Preference Approach (PPA) as a prelude to an actual randomized placebo-controlled trial of a cognitive-enhancing agent for patients with schizophrenia. This approach sought to test and enhance subjects' understanding of the key concepts of the trial, and administered the PPA at baseline and following a brief educational module. The motivations and concerns regarding potential participation in the proposed trial were also elicited by the PPA. Of one hundred ninety patients with schizophrenia recruited for this PPA study, only 12 (6.3%) were assessed to have understood all key trial-related concepts after the initial explanation and baseline PPA administration (prior to the educational module).

Following the education module, however, there was significant increase in the number of patients who understood all key trial elements. Younger age and higher level of education were significant factors associated with better understanding of the proposed trial. The main reasons cited for wishing to participate in clinical trials were personal medical benefits and altruistic desire to help others. Concerns regarding the safety of the trial medication were expressed in over 80% of the subjects. PPA administration with educational module supplementation may provide a valuable addition to clinical trial procedures in patients with schizophrenia.

Fig. 1. Reasons and concerns for volunteering in the clinical study ($n = 190$).

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3. Institutional Subjects

- Prisoners
- Students
- Nursing Home Patients

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Prisoners

- Study looking at prevalence of psychiatric diagnosis in prisoners

- Challenges:

✓ coercion (intentional or not)

✓ participation in the study cannot be used to influence sentencing or parole decisions

- The risks of participating must be as acceptable to non-prisoner participants as to prisoners.
- Selection of prisoners as subjects must be fair.
- Adequate follow-up care must be provided if needed.
- DSRB invited a prisoner representative, that is, someone who is knowledgeable of prison inmate life.

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Conclusions

- Ethical research is guided by the principles of justice, respect for persons, and beneficence.
- Vulnerable subjects should be included but also deserve special protections.
- Think carefully about the populations you plan to include in your research and take steps to ensure their rights and welfare are protected.

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Thank You

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