

Prisoner Research and the IRB

**Bertha deLanda
Research Compliance Office
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Prisoners in Research

Against historical background,

the selection of research subjects need to be scrutinized in order to determine whether a class is being **systematically selected** because of their:

- ▶ Easy availability
- ▶ Compromised position
- ▶ Ability to be manipulated



...rather than for reasons directly related to the problem being studied

Belmont Report, 1979

OHRP Guidance : 45 CFR 46, Subpart C

May 23, 2003

- ▶ Regs developed as a result of the **exploitation** of prisoners to test drugs and medical devices

90% of all pharmaceutical research was conducted on prisoners, who also were subjected to biochemical research

From 1962 to 1966, for example, 33 pharmaceutical companies tested 153 experimental drugs at Holmesburg Prison in Philadelphia



OHRP
Guidance

Our laminate contains sections A-I

A. General Regulatory Background

- **Additional protections** are provided

- Preamble notes:

*“most testimony before the Commission **opposed the use of prisoners** in any form of medical research not intended to benefit the individual prisoner”*

- Different from our understanding that there must be a **societal benefit** to research, and not necessarily a benefit to the individual
- **Limited research** would be permissible

B. Subpart C applies where any subject is or becomes a prisoner.

Applies:

- to any research **conducted or supported** by HHS
- whether the research involves individuals who are prisoners



at the **time of enrollment**

or **who become prisoners** after enrollment

- ▶ *Note : when someone becomes incarcerated during a study, this is a reportable event to the IRB (when the PD feels continued participation is necessary).*

C. Definition of “Prisoner”

“any individual

- **involuntarily confined or detained** in a penal institution
- detained in other facilities which provide **alternatives** to criminal prosecution or incarceration to a penal institution
- detained **pending** arraignment, trial or sentencing

NOTE:

- *for International research, we follow the regulations as a guidance*
- *this category can include political prisoners, people incarcerated for religious beliefs and POWs*



D. Special Composition of the IRB

- A majority of the board shall have no association to the prison institution
- When reviewing prisoner research, at least one panel member must be:
 - a prisoner
 - a former prisoner
 - a prisoner representative with appropriate background and experience



“has a close working knowledge, understanding or appreciation of prison conditions from the perspective of the prisoner”

45 CFR 46.304

E. Additional Duties of the IRB

The IRB must make seven additional findings

- I. Research under review represents one of four categories of “permissible research”

Under 45 CFR 46.306(a)(2)



E. Additional Duties, cont.

- ▶ 2. Any **advantages**...when compared to the general living conditions, are not of such a magnitude...that they **impair the subjects** ability to weigh risks/benefits
- ▶ 3. **Risks are commensurate** with risks that would be accepted by non-prisoner volunteers



E. Additional Duties, cont.

4. Procedures for subject selection within the prison are **fair and immune from arbitrary intervention** by prison authorities or prisoners

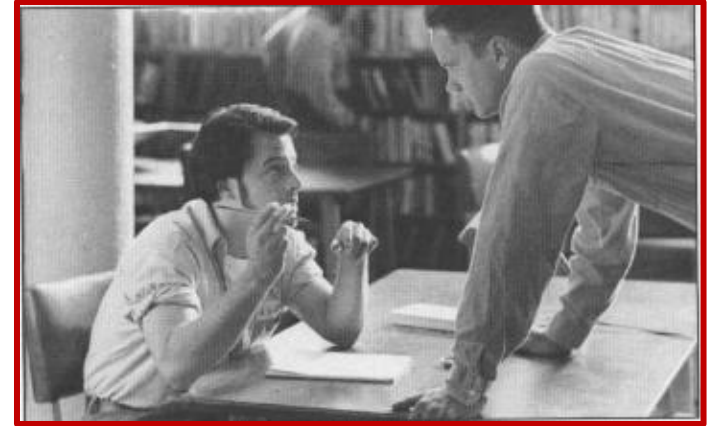
Control subjects **must** be selected randomly

UNLESS the investigator provides **justification** to the IRB in writing



E. Additional Duties, cont.

- Information is presented in language **understandable** to the subject population
- Adequate assurance that parole board **will not take participation into account** (when) making decisions regarding parole
Prisoners are made **aware** of this fact
- Adequate **provisions for follow up** procedures



F. Permitted Research Involving Prisoners

- 1 - **IRB must certify** to the Secretary of DHHS that the research was reviewed/approved
- 2 – Secretary must ascertain that it falls under **certain categories (4)**:



F.2 - Categories of Permissible Research (4)



- (i) studies **causes, effects, and processes** of incarceration and of criminal behavior
- (ii) **studying prison** as institutional structure **or** of **prisoners** as incarcerated persons

Both these categories present no more than minimal risk and minimal inconvenience

- (iii) condition under study **particularly affects prisoners**
- (iv) research has the **intent and reasonable probability** of improving health/well-being of the subject



G. Documentation of IRB Findings

The IRB must prepare and maintain adequate documentation of IRB activities.

- must make specific findings required under 45 CFR 46.305(a) (documented in the minutes)



H. Responsibilities of Institutions

- **IRB** maintains a record of the determination of the additional seven findings
- Required to send **OHRP** a certification letter

Research may not proceed until OHRP issues its approval in writing

I. Responsibilities of OHRP

- **OHRP** makes the determination which category the research falls under, and consults with appropriate experts