

Prisoners as Research Subjects

Past Research on Prisoners

Radiation Experiments These Atomic Energy Commission-funded studies in Oregon and Washington involved radiating testicles of prisoners, with follow-up biopsies (sometimes five or more). Some studies required vasectomies after completion of study procedures; some inmates refused. Occurred in 1950's to 1970's. These studies may have also involved NASA personnel. Oregon State Penitentiary inmates were paid \$25 for each biopsy, and a bonus of \$25 for the vasectomy at the end of the study; standard prison wages were 25¢/hour.

The Washington studies were conducted by Dr. C Alvin Paulson, and reviewed by a "human experimentation committee" at the University of Washington which was "informal" and conducted over the phone. The Chief of Research for the Dept of Institutions criticized the studies, stating, "There is no doubt but what the prison setting is ideal setting for this type of research...I suppose concentration camps provided ideal settings for the research conducted in them..." The study was terminated in Washington in 1970 after it was re-reviewed at the request of the Department; reviewers cited the ethical standards in the Nuremberg Code.

Pharmaceutical drug trials Pharmaceutical companies often built facilities on prison grounds to have easy access to prisoners. Until the early 70's, about 90% of pharmaceutical research was conducted with prisoners. Many trials were Phase I studies. Incentives provided to subjects were usually much higher than the rate paid for prison jobs, but less than non-prisoners would be paid for the same study. Prisoners often participated in more than one study at a time and were generally more likely to volunteer for higher risk research. Recruitment practices and informed consent were questionable. Very often prisoners served as recruiters and performed research procedures, so they could readily abuse the research environment to benefit their friends and get even with their prison enemies.

- *Acres of Skin* describes research on prisoners at Holmesburg Prison in Philadelphia from the 1950's-1970's. Most studies examined the effects of various chemicals on the skin, skin hardening experiments, fingernail extraction studies, chemical warfare agents, and high doses of dioxin and radioactive isotopes, as well as military trials of LSD and other mind-altering drugs. These studies were conducted by a renowned dermatologist, a prestigious university, major pharmaceutical and consumer product companies, the CIA, and the US Army.

"All I saw before me were acres of skin. It was like a farmer seeing a fertile field for the first time". (quote by U Penn researcher Dr. Albert Kligman)

Prison practices and institutions: These studies involved behavioral modification (electric shock, aversion, psychosurgery). Researchers saw criminal behavior as a sickness to be cured; the methods used were an attempt at rehabilitation. Researchers also focused on the spread of infectious or communicable disease in crowded conditions; they also infected prisoners with malaria and other disease to study the natural history of the disease. These studies did not have the intent to improve prison conditions or practices.

Forums on the ethical conduct of research with prisoners occurred as early as the early 1960's (before many of the examples cited above were even conducted).

Federal Regulations, 45 CFR Part C

"*Prisoner*" is defined in 45 CFR Part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

- The definition does not include persons on probation or parole, electronic monitoring, work release (e.g., restrictions on freedom imposed by state or local criminal justice authorities).
- The regulations apply when a human subject *becomes* a prisoner during his/her participation in research. The research must then be reviewed to ensure that it meets the requirements in Subpart C.
- A large proportion of prisoner research is unregulated.

"*Minimal Risk*" in prisoner research (45 CFR 46.303(d)) is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons".

- This definition differs from the definition of minimal risk in 45 CFR 46.102(i), in that it refers to physical or psychological harm and uses healthy (non-incarcerated) persons as the reference for assessment of risk.

Subpart C includes specific requirements for IRBs (see §304 and §305), and lists four areas of permissible research with prisoners (see §306). Institutions conducting research with prisoners must certify to OHRP that the IRB has fulfilled these requirements.

- These regulations apply only to research which is conducted or supported by HHS; research institutions, however, may indicate in their FWA that they will apply the requirements in the Subpart to research it reviews.

In 2003, the HHS Secretary approved a waiver for certain epidemiological research conducted or supported by HHS functions as a fifth category of permissible research. To qualify for the waiver, the research must have as its sole purpose to describe the prevalence or incidence of a disease by identifying all cases, or to study potential risk factor associations for a disease. The proposed research must pose no more than minimal risk to prisoners.

Issues to Consider in Research with Prisoners

Subject Selection: Does the researcher propose to conduct the research simply out of convenience? Is there adequate justification for including prisoners as subjects or for limiting subject selection to prisoners? Is sampling limited to sub-groups of prisoners, which may pose risks to subjects (e.g., sex offenders, etc.)? Selection for research, and the specific eligibility criteria for research, could become generally known to other prisoners, which could pose risk of stigma, perception of favoritism, etc.

Vulnerability: Prison populations are overwhelmingly minority, far beyond their representation in the general non-incarcerated population. Many are mentally ill, with little to no access to

meaningful treatment. Prisoners may also have lower levels of educational attainment, low literacy/illiteracy, and learning problems. Many abuse drugs and alcohol. Prisoners are also vulnerable to favoritism or retaliation within the inmate population for anything outside "accepted" inmate behaviors.

Risks: Prisoners may assume greater risk than non-incarcerated persons. The lack of control over their daily lives may make prisoners more likely to accept "riskier" research that a healthy, non-incarcerated population would not. Research participation could be seen in the inmate population as being accommodating to corrections staff or prison administration, or as setting oneself "apart" from the rest.

Incentives: Even modest incentives may create undue influence to participate in research. Prison pay scales, for those who work, are only fractions of what a non-incarcerated person would make. In addition, many prisoners pay restitution for their crimes, child support, the costs of incarceration, etc. Incentives such as a candy bar may be meaningful in a prison setting, but not outside the prison context. In general, prisoners are not allowed to receive cash; however, a cash contribution to a prison program that benefits all prisoners may be appropriate.

Confidentiality and Privacy: Prison records may be accessible to a wide variety of corrections staff, medical staff, and even other inmates. Mail may be opened or censored. Telephone calls may be monitored. Access to private areas to interview subjects or carry out study procedures may be limited (or could even pose risks to the researchers). Investigators should provide a clear description of the prison environment in which they propose to conduct the research. Reviewers should consider whether a Certificate of Confidentiality would provide additional protection to research records.

Undue Influence/Coercion: Prisoners do not have choice in virtually any aspect of their daily lives. Research may present the opportunity to appear "cooperative" to prison authorities or to interact with someone new, or even to leave the cellblock. Research may provide a break in routine, a novel activity.

Autonomy: It should not be assumed that prisoners are incapable of making an informed decision about research participation. Reviewers should avoid "over-protecting" potential research subjects just because they are incarcerated.

Future Changes to the Federal Regulations??

The Institute of Medicine was given the task of assessing whether the ethical basis for research with prisoners differs from those for non-prisoners, to develop an ethical framework, and to identify appropriate safeguards, given the changes in incarceration and prison populations since the National Commission issued its report in 1979. The IOM found the current system of oversight "deficient", and made the following recommendations:

- Expanding the definition of "prisoner" to include a larger group of persons whose freedom is restricted due to sentencing, probation, parole, or community placement.
- Ensure consistent, universal protection, so that ethical standards apply regardless of source of research funding
- Change the determination of acceptable research to a risk/benefit analysis, rather than a categorical standard
- Include an approach of "collaborative" responsibility, which includes prisoners and prison staff.
- Enhance oversight to ensure a more rigorous system than the current system of IRBs.

Sources:

Acres of Skin: Human Experiments at Holmesburg Prison: A True Story of Abuse and Exploitation in the Name of Medical Science. Allen M Hornblum. Routledge, 1998

Advisory Committee on Human Radiation Experiments, <http://www.gwu.edu/~nsarchiv/radiation/>

Ethical Considerations for Research Involving Prisoners. Institute of Medicine. National Academies Press, 2007.

Moser, DJ, Arndt, S, Kanz, JE et al. "Coercion and Informed Consent in Research Involving Prisoners" *Comprehensive Psychiatry* Vol 45(1), 1-9 (January 2004)

Office of Human Research Protections IRB Guidebook, Chapter VI, Special Classes of Subjects, http://www.hhs.gov/ohrp/irb/irb_chapter6.htm

Stanford Prison Experiment, A Simulation Study of the Psychology of Imprisonment Conducted at Stanford University <http://www.prisonexp.org/>

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