

Issue Brief

Protection of Vulnerable Populations: Research Involving Prisoners

Albert J. Grudzinskas, Jr., JD and Jonathan C. Clayfield, MA, LMHC

The attitude that, “it is not cruel to inflict on a few criminals, sufferings which may benefit multitudes of innocent people through all centuries,” has prevailed in the area of research involving prisoners through history.¹ The very nature of incarceration – controlled diet and living conditions, subject availability, etc. – make prisoners an attractive population to study. There are, however, special considerations when prisoners participate in research that must be addressed to ensure their protection as human subjects. This brief will explore some of the issues critical to working with prisoners in research, will discuss the standards of informed consent and competency, especially as they relate to persons with mental illness, and will provide suggestions to researchers for conducting ethical and cogent research with prisoners. For the purposes of this Brief, the term prisoner encompasses all individuals detained in penal institutions and in other facilities by virtue of statutes or commitment procedures, e.g., to a psychiatric hospital, which provide alternatives to criminal prosecution or incarceration.

Concerns when Prisoners are Subjects of Research

In 1975, the National Prison Project of the American Civil Liberties Union found that 85% of the total subjects first tested to demonstrate the safety of new drugs were prisoners.² This finding led the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to issue the Belmont Report, which contained regulations significantly limiting prisoner involvement in research.³

The Belmont Report identified three basic ethical principles critical to any research conducted with human subjects and, in particular, prisoners: *respect for persons, beneficence and justice.*

Respect for persons holds that each individual is autonomous and should be treated as free to make his or her own choices. The nature of prison, however, leads to restrictions on autonomy. For example, while paying subjects to participate in research is considered ethically acceptable, prisoners may be unduly influenced or enticed by the monetary gain of participation given that prisoners typically earn far less for other “work” activities. Careful consideration should be given to an individual’s ability to make autonomous decisions in light of the possible coercion inherent in a specific environment or setting. By the same token, paying prisoners less money to participate than non-prisoners can be viewed as exploitive. It is important to remember payment should not be viewed as a benefit, but rather as compensation for participation.⁴

Beneficence requires that any potential risks of harm in a study are balanced against any benefits that may be gained. For example, a study of the origins of violence may expose an individual to risk, e.g., further prosecution, particularly if the violence constitutes an unreported crime. In this example, researchers may need to consider methods that reduce such risks to confidentiality, e.g., can the same results be obtained by asking less sensitive questions? “The problem posed...is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.”⁵

Justice involves the fairness of the distribution of the risk and benefit of study participation. The participant selection process for a study should include consideration of whether the benefit of the study will positively impact the population being studied, or whether participants are selected just

for the researcher's convenience. If the latter, the research reflects an unjust distribution of risk and benefit.⁶

Informed Consent and Competency

To ensure that human subject participation is voluntary, consent by the participant must be informed, i.e., freely given in a knowing, intelligent and voluntary manner.⁷ Competency is a person being able to evidence a choice, have a factual understanding of the nature of the issue being considered, exhibit an ability to rationally manipulate the information provided, and demonstrate an appreciation of the nature of the situation and its import to the person making the choice.⁷ Researchers are urged to look to the laws of their particular jurisdiction before proceeding to accept someone's consent as being competent and therefore informed.

Informed Consent and Competency for Persons with Mental Illness

The National Mental Health Association's current policy regarding mental health treatment in correctional facilities states that, "Under no circumstances should prisoners be the subjects for medical research without proper ethical review and informed consent."⁸ Persons with psychiatric disorders, however, may lack the capacity to understand what interviewers are asking them to do or to make reasoned decisions about participation.⁹ There are no specific additional regulations pertaining to using prisoners with mental illness as human subjects even though the presence of mental illness can complicate the determination of a person's competency to give his or her informed consent.⁹ Given the high number of prisoners experiencing mental illness (estimates of over 283,000 inmates in U.S. state and federal prisons),¹⁰ this is an important concern for any researcher working with the prison population.

Considerations for Researchers and IRBs

Researchers and Institutional Review Boards (IRBs) have additional responsibilities when reviewing research involving prisoners, especially prisoners with mental illness, where they must consider whether:

- the research on cognitively disabled persons as subjects (e.g., prisoners with mental illness) bears some relationship to their situation (e.g., a study on how prison life impacts prisoners with mental illness);
- the advantages to prisoners from participation in the research study impair the ability to freely choose to participate (e.g., a prisoner may agree to participate in a study because it pays well, ignoring the risks of the study). Does the study provide sufficient informed consent protocols to make sure the participant fully understands the risks?;¹¹

- the risks involved in the research are commensurate with risks that would be accepted by non-prisoners;
- the procedures for selecting subjects are fair and immune from arbitrary intervention by prison authorities or other prisoners. For example, parole boards should not take a prisoner's participation in a research study into account when making parole decisions and researchers should make sure study participants truly understand this; and
- there should be full disclosure to research subjects. Ideally, the basis for assessing participant consent should involve full disclosure of the procedure about to be undertaken. A person can only weigh the risks and benefits of a procedure if he or she has been fully apprised of each. While recognizing that there may be instances where full disclosure could invalidate the purpose of a study (e.g., participants knowing whether they are taking an experimental medication or a placebo), it is important to determine whether full disclosure is being avoided because it is truly necessary or because it inconveniences the investigator.

References

1. Celsus, 1st Century AD, (Ancient Rome as quoted in "Evolving Protections for Human Subjects: From Dachau to Tuskegee to Penn to Hopkins" Primer IRB 101 On the Road, D. Nelson, Presentation to University of Massachusetts Medical School, December 3, 2002.
2. Wertheimer, A. (1987). *Coercion Studies in Moral, Political and Legal Philosophy*. Princeton, NJ: Princeton University Press.
3. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the Belmont Report (April 18, 1979).
4. Grudzinskas, A.J. (2003). *Prisoners as Human Subjects Handbook*. Center for Mental Health Services & Criminal Justice Research, the State University of New Jersey – Rutgers.
5. The Belmont Report, Note 3.
6. 45 Code of Federal Regulations (CFR) 46.303
7. Appelbaum, P.S. & Roth, L.H. (1982). Competency to Consent to Research. *Archives of General Psychiatry*, 39, 951-958; and Appelbaum, P.S. & Grisso, T. (1988). Assessing Patients' Capacities to Consent to Treatment. *New England Journal of Medicine*, 319(25), 1635-1638.
8. NMHA Policy Positions: Mental Health Treatment in Correctional Facilities (March 12, 2004). Available at <http://www.nmha.org/position/ps55.cfm>.
9. Sieber, J.E. (June, 2001). Summary of Human Subjects Protection Issues Related to Large Sample Surveys, U.S. Department of Justice, Bureau of Justice Statistics, NCJ 187692, available at <http://www.ojp.usdoj.gov/bjs/pub/pdf/shspirls.pdf>
10. Ditton, P.M. (1999). *Mental Health and Treatment of Inmates and Probationers*. Bureau of Justice Statistics, U.S. Dept. of Justice, Washington, DC.
11. 45 CFR 46.305 et. seq.

Visit us on-line at www.umassmed.edu/cmhsr