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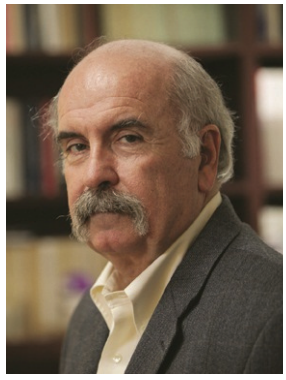

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Clinical trials involving prisoners: a bioethical perspective

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Since the Belmont report in 1979, protections for research participants in the USA have continued to advance and increase awareness among public and research communities about the importance of safeguards for special research-subject populations, particularly those with greater potential for exploitation [101]. Prisoners are one of those special populations due to their restrained liberties and potential for being abused. Unless additional safeguards are implemented and constantly monitored, prisoners will continue to be at risk of being coerced into participating as research subjects. However, with proper procedures and due diligence, prisoners' choices about research participation can be informed, deliberate and voluntary. Prisoners should be afforded the opportunity to participate in biomedical and behavioral research, but only under conditions assuring adherence to accepted current and future bioethical principles.

As with women who are pregnant, human fetuses, neonates, and children, indubitably, prisoners are a 'vulnerable' research population that needs protection from potential abuse. Inmates often find themselves in situations where they are unable to protect their own interests, such as feeling pressured by a correctional officer to complete a task or possibly face sanctions for noncompliance. But the potential for abuse should not equate to what has been perceived by some as a prohibition against research involving prisoners. Unquestionably, there have been major problems and concerns with the way some research has been conducted within prisons, but this does not mean that these problems cannot be addressed, thereby allowing researchers the opportunities to find significant and meaningful ways to improve inmate health and well-being through clinical trials.

The benefits of research involving prisoners have been noteworthy and have positively impacted the prison population as well as society in general. For example, years of studies involving HIV-positive inmates have resulted in the successful implementation of testing and intervention strategies that have led to a 75% reduction in AIDS-related deaths, a decline that is similar to what has been seen in the community [1]. Building on these scientific achievements, the National Institute on Drug Abuse (MD, USA) is now focusing on implementing and evaluating a 'seek, test, treat, and retain' paradigm in criminal justice populations with several projects designed to help HIV-positive inmates maintain viral suppression after release from prison; a high-risk period when interruption of antiretroviral therapy is common and improved adherence strategies are sorely needed. Without the benefits of these research efforts, HIV-positive inmates would most likely not receive the testing and on-going treatment they need, and consequently, would continue to be infectious, posing a public health threat after release.

Unfortunately, prisoner research has been disgraced by unscrupulous experiments in the past, such as the dermatological studies in Philadelphia's Holmesburg Prison. These experiments included paying inmates large sums of money to participate in a

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variety of procedures, including the use of radioactive substances and known poisons; trials that clearly were not designed to provide the participants with any direct benefits from their participation [2].

Due to the ongoing issues involving prisoners as research subjects, the Institute of Medicine (IOM) was commissioned to examine the ethical bases for prisoner research and formulated recommendations and actions to help further protect prisoners involved in research [3]. The IOM call to expand the definition of a prisoner is an excellent example of the progression of bioethical principles regarding vulnerable populations. Currently, there is a lack of recognition by many researchers about the vulnerabilities of the nonincarcerated who are under sanctions from the criminal justice system. They are also susceptible to abuse because of their constrained autonomy. Despite their lack of incarceration, they function within a tightly controlled environment of supervision and may perceive research participation as compulsory if they sense that the 'system' might favor their participation. Their freedom of choice may not be as restricted as prisoners; however, their options are limited and more restricted than individuals who have no involvement with the criminal justice system.

Frequently, researchers view regulations governing the participation of prisoners in research as barriers and burdensome and opt to conduct their clinical trials with nonprisoner populations. We, however, believe that this is mostly because of a misperception of current rules and regulations and, with the proper amount of time and instruction, an appropriate understanding can be achieved and these perceived barriers and burdens can be overcome. Requirements for the protections of prisoners involved in research are honorable, necessary, and should be seen as a standard and common ethical practice that is part of the research enterprise. Clinical research should always put the welfare and well-being of subjects first and foremost, and it needs to clearly show the direct benefits to the prisoners involved in the research. Prisoners should not be included in research studies simply because they represent a sample of convenience.

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The time has come to accept the protections needed to conduct prisoner research similar to the acceptance that has already become routine for the protections needed for noncriminal justice populations (e.g., institutional review boards, protocols, reviews, data and safety monitoring plans, data and safety monitoring boards, or stopping a trial). Ideally, as noted by the IOM, a benefit-to-risk ratio should be used to determine the ethical acceptability of prisoner research, so that when the benefits outweigh the risks, the research would be permitted. Chronic health conditions such as drug addiction, hepatitis C and HIV are disproportionately represented in the prisoner population and trials involving these conditions would be acceptable when benefits eclipse risks. Medication trials, such as injectable naltrexone for treating alcohol dependence among soon to be released prisoners, under such a benefit–risk scenario, would be allowed. Although some studies under the current category-based regulatory system might be determined as high risk, the possibility of being allowable and approved in a timely manner needs to be afforded when there is sufficient evidence of direct benefits for prisoners participating in the research.

As Elger and Spaulding noted in their 2010 Bioethics special supplement [4], revisiting guidelines does not mean eliminating restrictions. In fact, they advocate a procedure similar to the European approach, including the prohibition of prisoner research that provides no direct benefit to prisoners. Indeed, prisoners need to be able to benefit from the research, and policies must be in place to protect them, including regulations prohibiting excessive participant incentives, such as large financial incentives or the opportunity for earlier release. While speculation that this is not possible may fuel the on-going debate over the bioethics of conducting prisoner research, the reality is that ethical research can and does occur. In our studies involving prisoners, data-collection procedures are stringent and require careful monitoring, with a focus on the voluntary nature of participation. One-on-one interviews with study participants, for example, must occur in private settings within the prison where correctional staff are not able to hear the interview, yet also be conducted within view of correctional staff for security and safety purposes.

The bioethical debate over prisoner research will no doubt continue, but the debate cannot ignore the prisoners' right to participate in research and forget how they might benefit from the findings. Fears of exploitation should not preclude the circumstances under which prisoners can benefit from science. Tight regulations are necessary, such as insisting that consent and participation must be completely voluntary and incentives be limited so that they are not coercive, but these regulations should not inhibit studies that pose more than 'minimal' risk if benefits exceed risks. Clearly, the general public and research community can greatly benefit from an education initiative focused on prisoner research and ethical conduct

when interacting with individuals whose liberties are suppressed.

These are complicated issues, but we are convinced that there is a tremendous need for scientifically sound research involving prisoners, that it can be conducted and that it should be closely monitored. Given the recent US Department of Health and Human Services announcement regarding a proposal to improve rules protecting human research subjects, the opportune hour is near for policy changes to emerge that will further advance critically important research involving prisoners as subjects [102].

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