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US ponders unlocking the gates to prisoner research

The US government is for the first time in nearly 30 years considering revising the rules that govern research on prisoners. The current regulations almost entirely forbid such research, but the potential for exploitation still makes some experts balk at the idea of loosening the rules.

Under the existing rules, prisoners can only participate in research that either directly benefits them or involves matters, such as AIDS, that disproportionately affect them. The guidelines also mandate that every study be examined by an institutional review board that includes a prisoner representative.

Although the rules are designed to protect prisoners from the egregious abuses of the past, some experts say they prevent inmates from participating in legitimate studies.

"The current regulations are very, very protective of prisoners," says Julia Gorey, a policy analyst in the Office for Human Research Protections in the HHS. "Some voices in the community have argued they are an inappropriate disincentive to researchers."

The Department of Health and Human Services (HHS) in 2004 asked an Institute of Medicine committee to revisit the issues and recommend new rules. The committee met for the last time on 8 December and plans to submit its report in March 2006. Members say they've heard passionate arguments on both sides, but decline to reveal what the committee's recommendation is likely to be.

Dark past

The HHS set the current regulations in place in 1978 in response to reports of appalling prisoner abuse. Researchers are said to have burned prisoners to imitate the effects of atomic explosions, exposed them to radiation, injected them with live cancer cells and tested behavior-modification techniques such as castration and electric shock.

After those rules went into effect, research on prisoners slowed dramatically. The rules only applied to studies funded by federal money, but many states and correctional bodies adopted them, and added a few of their own, creating a near ban on prisoner research. Exact numbers are difficult to obtain, however, because there

has never been a comprehensive count of how many studies in the US involve prisoners.

Because of the potential for prisoner abuse, many experts are still skittish about relaxing the rules. "I've seen too many cases where good people can do some very damaging things," says Allen Hornblum, a medical ethicist at Temple University who documented some of the abuses in his book *Acres of Skin*. "I'm going to do my best to articulate that [the HHS] should not open up those prison doors for research. I have great fears that they're going to turn back the clock."



Knotty problem: Rules to protect prisoners from exploitation leave scientists' hands tied.

But in trying to protect prisoners, the pendulum has perhaps swung too far in the other direction, others contend.

Researchers who manage to clear their studies with the HHS, state governments and the correctional facilities still run into practical problems. For instance, Mary Woods Byrne, a professor of clinical nursing at Columbia University who has conducted research on prisoners, says that after she would get clearance from a facility's warden, security guards at different stages of her entry would sometimes detain her or send her home.

Researchers' most common complaint, says Greg Koski, former director of the Office of Human Research Protections, is that the

regulations prohibit them from conducting studies that might benefit prisoners. For instance, studies on diseases that disproportionately affect prisoners may help researchers devise specific interventions.

The right thing

The rules also give little leeway for prisoners to volunteer for studies. Prisoners might participate in studies to get individualized healthcare attention or as a distraction from boredom or prison jobs. Some might consider it a way to give back to society.

In Europe, access to clinical trials is considered a prisoner's right, notes Bernice Elger, a researcher at the prison medicine department of the University Hospital of Geneva. In most countries in Europe, researchers can conduct studies in prisons as long as they can show that a given study has some benefit to prisoners, that risks are minimal and that there is a necessity to do it in a prison, she says.

The debate raises the question: will the HHS loosen the rules? Officials decline to reveal what the agency might decide, saying they are merely revising the rules to accommodate a changing penal system. "The whole structure is being examined for revision, not necessarily as a loosening or tightening," Gorey says.

In the meantime, committee members are also examining the changing definition of the term 'prisoner'. In recent years, criminal justice systems have come up with new forms of incarceration, including electronic monitoring systems, home confinement, work release programs, halfway houses and court-mandated drug treatment, making the concept of prison more complex.

As the debate continues, some say the best decision would be to leave the rules unaltered. "This is the least opportune time to decide if we should change the rules," says Dan Wikler, a Harvard University bioethicist who noted the abuses at Abu Ghraib. "Prisons are closed institutions and no one knows what's going inside," so expecting that all researchers will conduct experiments ethically behind prison walls is wishful thinking, he says. "We have not reached a stage of enlightenment."

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