Published in final edited form as:

Am J Bioeth. 2017 July ; 17(7): 55–57. doi:10.1080/15265161.2017.1328534.

“The Indefinite ‘Stay’ on Regulatory Reforms for Research with Prisoners”

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The verdict is in, so-to-speak. The Department of Health and Human Services (HHS) has issued the 2018 Common Rule, which purportedly “allows more flexibility in keeping with today’s dynamic research environment” (HHS 2017). When reforms for research regulations come “once in a lifetime” (Capron 2017), a high bar should be met before kicking the can further down the road. Yet, as HHS acknowledged, “[t]he final rule does not make revisions to the HHS regulations at 45 CFR part 46, subparts B, C, and D” (Federal Policy for the Protection of Human Subjects 2017, 7183). Thus, individuals within the vulnerable populations governed by these additional subparts are categorically excluded from long overdue updates needed to improve oversight and facilitate modern-day research. With its decision to restrict the reform efforts exclusively to subpart A, HHS has effectively imposed an indefinite “stay” on regulatory reforms for prisoners. While this outcome is not surprising and was foreshadowed by the minimal attention given to consideration of research needs and interests of prisoners in the 2011 ANPRM and 2015 NPRM, it is nevertheless a disappointing missed opportunity that warrants criticism.

Before the mid-1970s, advancing the overall good of society was often prioritized over consideration of potential harms to individual subjects (Lerner 2007, 1806). Accordingly, exploitative research practices on prisoners—such as exposing them to chemical warfare agents and viral infections to better understand various diseases—were rampant prior to the codification of the Common Rule. As we recently indicated, the pre-2018 Common Rule was the product of a desire to protect individuals *from* research rather than a resolute attempt to promote individuals’ rights *to* and *in* research (Huang, Cauley, and Wagner 2017, 8). Unfortunately, this protectionist framing resulted in an over-correction and the imposition of administrative burdens dramatically limiting prisoners’ inclusion in biomedical research. Due to the disproportionately large impact of mass incarceration on racial and ethnic minorities, discrepancies regarding access to research opportunities and healthcare have and will continue to manifest in entrenching pre-existing inequalities. Because research with prisoners is only permitted under subpart C if it involves minimal risk and fits within one of four narrowly defined categories, the regulatory restrictions against participation in experiments (such as clinical trials for life-saving treatments or longitudinal studies intended

to assess health outcomes or improve health care delivery) only serve to exacerbate health disparities between prisoner and non-prisoner populations. Recognizing that such a protectionist approach frustrates rather than facilitates the exercise of prisoners' autonomy and concurrently denies prisoners a fair distribution of the risks and benefits of science, we specifically advocated for recognition and restoration of research participatory rights. As HHS has acknowledged, research has "changed considerably" since the federal policy was first adopted and "[m]ore people want to play an active role in research, particularly related to health" (Federal Policy for the Protection of Human Subjects 2017, 7218). Along with other considerations, these contemporary realities weaken justifications for these outdated protectionist regulations. Indeed, if subpart C were created with the intention of upholding the welfare of prisoners, then there is a need to recalibrate the regulations so they properly fulfill (rather than impede progress towards) that purpose.

We are not alone in our criticism of the category-based approach of subpart C. In 2007 the Institute of Medicine issued its report "Ethical Considerations for Research Involving Prisoners," which includes recommendations for a risk-based approach to replace the category-based approach, promotion of "collaborative responsibility," and "proactive monitoring by IRBs" (Committee on Ethical Considerations for Revisions to DHHS Regulations for Protection of Prisoners Involved in Research 2007). These proposed changes do not signal a movement away from protecting prisoners; rather, they aim to improve prisoners' participatory rights while continuing to recognize their vulnerable status. Public comments on the ANPRM and NPRM raised additional concerns regarding overly protectionist policies, with commentators noting "Prisoners are currently over-protected to the point of justice inequities in research" and "blanket pronouncements may exclude individuals with [vulnerable] characteristics from participating in research, in violation of the Belmont Principle of respect for persons and their right to choose" (Huang, Cauley, and Wagner 2017, 11).

Unfortunately, HHS made no direct changes to subpart C and, in so doing, exhibited a blatant disregard for the need to recalibrate these regulations (an omission all the more reprehensible given that rules remain "largely static for decades" (Berkman et al. 2017)). HHS made but one change affecting research involving prisoners: while the pre-2018 Common Rule did not permit the application of regulatory exemptions to be applied to prisoners, HHS added an exception at §__104(b)(2) to allow the regulatory exemptions to be applied in the limited occasion when prisoners are involved in research only "incidentally." The relevant text of the 2018 Common Rule is as follows:

The exemptions at this section do not apply to research subject to subpart C, except for research aimed at involving a broader subject population that only incidentally includes prisoners (Federal Policy for the Protection of Human Subjects 2017, 7261).

Reduction of administrative burden rather than participatory rights of prisoners seemed to be the impetus for this minor change (Federal Policy for the Protection of Human Subjects 2017). It is frustrating that, since passage of subpart C, HHS has virtually ignored the applicability of evolving research dynamics to prisoners. This lack of attention implies a

misguided assumption that insulating prisoners from research alone guarantees everlasting justice and promotion of their welfare.

Though HHS characterizes the 2018 Common Rule as involving a “narrow expansion” (Federal Policy for the Protection of Human Subjects 2017, 7183) of research with prisoners through the applicability of some exemption categories, we can hardly regard this change as meaningful when viewed from a prisoner’s perspective. While the trivial change permits researchers to continue to conduct *secondary* analysis of biospecimens and data collected for research without regard to whether participants who provided the biospecimens and data later become incarcerated, the new rule does not soften the harsh penalty that *all* research activities must be suspended upon a participant’s incarceration—even if the research activities are merely communication (such as updates about a longitudinal study, announcements for research activities available to enrolled participants, or return of results to participants) or activities that, on their own, would have been exempt activities (such as the submission of participant provided information via surveys). Subpart C requirements for research that *intentionally* involves prisoners remain unmodernized, and the practical challenges for researchers planning longitudinal studies that are *not* eligible for exemption (such as the Precision Medicine Initiative® *All of Us*SM Research Program) persist. The federal policy in its current form disincentivizes researchers from designing studies that evaluate factors uniquely caused or influenced by the prison environment. At a time when bioethicists are increasingly recognizing the importance of promoting equitable research practices through participatory science, it is absurd that the reforms would effectively punish those researchers who acknowledge the sociopolitical environment in which biomedical research is conducted today (*i.e.*, a society in which the criminal justice system disproportionately affects the lives – and frustrates the research participatory rights – of individuals of racial and ethnic minorities) and seek to involve prisoners in biomedical research intentionally. Moreover, the issue of health disparities is especially glaring in light of the recent push for genomics enabled learning health care systems, which offer “unprecedented opportunity for practitioners to customize treatment options for patients based on their genetic signatures” (Roundtable on Translating Genomic-Based Research for Health 2015, 1) through integration of genomic data into healthcare research. Bidirectional feedback of the analysis of data, which entails frequent engagement with patients for sharing data and understanding patient preferences, is nearly impossible with prisoners under subpart C regulations. Denying prisoners the right to access these benefits of rapidly advancing healthcare signals not only disregard for incarceration as a “juridic disability” that removes individuals from the societal context in which they are in a position to help themselves but also, as precision medicine becomes routinized, arguably infringes upon prisoners’ constitutionally protected right to adequate healthcare (Huang, Cauley, and Wagner 2017). Moreover, had reforms been made to subpart C to facilitate participation in research, prisoners could have benefited from research participation as one means of rehabilitation and reintegration: communicating with researchers holds the potential to foster learning opportunities and help prisoners manage their own health, and allowing for their participation in research (which is increasingly social) could strengthen prisoners’ ties to families, communities, and society at large.

While Capron remarks in this issue, “So, at last, the wait is over” (Capron 2017), for prisoners the wait continues. It is unlikely that HHS’s assertion that its “intent is to eventually amend the other subparts” brings much comfort to the millions of individuals incarcerated in the United States who directly experience the exclusionary force of the status quo. The vague timeline for this purported change does not correspond to the level of urgency appropriate for dealing with either the health disparities between prisoner and non-prisoner populations or the criminal justice system as a form of structural discrimination in biomedical research and health care. While the practices of research exploitation that led to the introduction of subpart C remain reprehensible and to be avoided, the continued status quo of research exclusion of prisoners and their spaces perpetuates an “out of sight, out of mind” attitude that exacerbates health disparities and denies significant segments of our population fair opportunities to contribute to scientific discoveries and share in resulting benefits. The indefinite stay on research regulations for prisoners must be lifted, accompanied by a recalibration of the 2018 Common Rule and subpart C.

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