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REFORM IS BIOMEDICAL RESEARCH**

**Paul Litton**

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## ON THE ARGUMENT THAT EXECUTION PROTOCOL REFORM IS BIOMEDICAL RESEARCH

Paul Litton\*

### INTRODUCTION

The United States Supreme Court just decided *Glossip v. Gross*,<sup>1</sup> rejecting the claim that Oklahoma's lethal injection protocol violates the Eighth Amendment. Like Kentucky's protocol approved in *Baze v. Rees*,<sup>2</sup> Oklahoma's procedure involves the administration of three drugs, the second and third of which paralyze an inmate and then stop his heart, respectively. The third drug in both protocols, potassium chloride, would cause excruciating burning pain if an inmate were not properly anesthetized, as it flows through his veins. The difference between the Kentucky protocol permitted in *Baze* and the Oklahoma procedure permitted in *Glossip* is the first drug. Kentucky employed sodium thiopental, "a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection."<sup>3</sup> Oklahoma's first drug is midazolam, which is a benzodiazepine, like Valium; it is not a barbiturate. Midazolam is used primarily to relieve anxiety and to sedate, not to "induce the type of deep, general anesthesia needed to withstand painful stimuli,"<sup>4</sup> such as the burning pain caused by potassium chloride. The pain from the

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\* R.B. Price Professor of Law, University of Missouri School of Law. Many thanks to Seema Shah for the opportunity to comment on her excellent article. I am also grateful to the editors of *Washington Law Review* for very helpful comments on prior drafts.

1. No. 14-7955, 2015 WL 2473454 (U.S. June 29, 2015).

2. 553 U.S. 35 (2008).

3. *Id.* at 44.

4. David B. Waisel & Paul Litton, *Why the Lethal Injection Drug Debated by the Supreme Court Today is Unconstitutional*, THE NEW REPUBLIC (Apr. 29, 2015), <http://www.newrepublic.com/article/121656/glossip-v-gross-will-determine-constitutionality-lethal-injection>.

potassium chloride can “break through the midazolam-induced sedation,” causing the inmate to regain consciousness.<sup>5</sup> Midazolam was used in at least three executions that have gone terribly wrong over the last year.<sup>6</sup>

Condemned inmates in *Glossip* argued that Oklahoma’s use of Midazolam as the first drug violates the Eighth Amendment because it creates a “substantial risk of serious harm.”<sup>7</sup> According to the plurality in *Baze v. Rees*, an execution method is unconstitutional if it presents a “substantial risk of serious harm,” which is defined as an “‘objectively intolerable risk of harm’ that prevents prison officials from pleading that they were ‘subjectively blameless for purposes of the Eighth Amendment.’”<sup>8</sup> In addition to arguing that the Oklahoma protocol presents a “substantial risk of serious harm,” petitioners in *Glossip* bolstered their claim that the Oklahoma Department of Corrections is subjectively blameworthy because of the way in which it chose midazolam.<sup>9</sup> At the preliminary injunction hearing before the federal district court, former general counsel for the Oklahoma Department of Corrections (ODOC) testified that he, along with the Attorney General’s office, chose midazolam because “we knew [it] had the same properties as pentobarbital as far as sedation goes.”<sup>10</sup> The truth is that they did not know. Pentobarbital, like sodium thiopental, is a barbiturate; midazolam’s properties, in terms of the kind of unconsciousness it causes, are different.<sup>11</sup> Accordingly, petitioners in *Glossip* argued that the ODOC chose midazolam based on inadequate investigation, lacking the knowledge required to make a responsible and legally permissible decision about the execution protocol.<sup>12</sup>

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5. *Id.*

6. Jason Millman, *The Botched Executions Behind the Supreme Court Case on Lethal Injection*, WASHINGTON POST WONKBLOG (Jan. 23, 2015), <http://www.washingtonpost.com/blogs/wonkblog/wp/2015/01/23/the-botched-executions-that-make-people-think-lethal-injection-is-cruel-and-unusual/>; Ben Crair, *2014 Is Already the Worst Year in the History of Lethal Injection*, THE NEW REPUBLIC (July 24, 2014), <http://www.newrepublic.com/article/121656/glossip-v-gross-will-determine-constitutionality-lethal-injection>.

7. Brief of Petitioner at 25, *Warner v. Gross*, 776 F.3d 721 (10th Cir. 2015) (No. 14–6244), *aff’d sub nom.* *Glossip v. Gross*, No. 14-7955, 2015 WL 2473454 (U.S. June 29, 2015) (citing *Baze v. Rees*, 553 U.S. 35, 50 (2008)).

8. *Baze*, 553 U.S. at 50 (quoting *Farmer v. Brennan*, 511 U.S. 825, 846 n.9 (1994)).

9. See Brief of Petitioner, *supra* note 7, at 11.

10. Transcript of Preliminary Injunction Hearing at 287, *Warner v. Gross*, 2014 WL 7671680 (W.D. Okla. Dec. 22, 2014) (No. CIV-14-665-F), available at [https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/Glossip/documents/2014-12-17WARNER1\(RT\)\(FINAL\).pdf](https://www.law.berkeley.edu/clinics/dpclinic/LethalInjection/LI/Glossip/documents/2014-12-17WARNER1(RT)(FINAL).pdf).

11. Brief of Petitioner, *supra* note 7, at 2–3 (citing *Baze*, 553 U.S. at 50).

12. *Id.* at 10–11.

Regardless of whether the Supreme Court rightly decided *Glossip*, Oklahoma officials had inadequate reason to choose midazolam as the first drug. Its decision to try midazolam is one example illustrating Seema Shah's point that death penalty states, in using new drugs and drug combinations, are engaged in "poorly designed experimentation that is not based on evidence."<sup>13</sup> Shah argues that "an important factor" causing the high rate of botched executions is that the lethal injection reform in which states are engaged is a type of human subjects research that is going unregulated.<sup>14</sup>

Shah's arguments in *Experimental Execution* are creative and thought-provoking. Their importance resides in the fact that all possible legal avenues should be identified and explored for prohibiting reckless choices by departments of corrections in their design of execution protocols. Shah's work, appealing to ethical and legal principles governing human subjects research, is one such worthy exploration. Her claim that recent reforms constitute research has strong intuitive appeal. As she writes:

All states conducting executions . . . borrow and learn from one another's experiences and tend to change their protocols by adopting the same new drugs around the same time. This suggests that states are making modifications and experimenting with the goal of producing knowledge from each individual execution to improve future executions.<sup>15</sup>

As evidence of the value of her exploration into the application of research ethics and law, we see attorneys for death row inmates urging courts to consider recent lethal injection reforms as unnecessarily risky human subjects research. The plaintiffs in *Glossip*, for example, argued that the "State's hasty, ill-founded, non-medical approach to the selection of midazolam as an execution drug, does not accord with basic expectations of research."<sup>16</sup>

Part I of this essay grants Shah's conclusion that death penalty states are engaged in human subjects research. However, it argues that if protocol reform amounts to research, then it is unethical for lacking social value, regardless of the morality of capital punishment. Shah argues that research ethical requirements, such as informed consent and Institutional Review Board (IRB) review, are necessary to render the

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13. Seema K. Shah, *Experimental Execution*, 90 WASH. L. REV. 147, 147 (2015).

14. *Id.*

15. *Id.* at 182.

16. Brief of Appellant at 13, *Warner v. Gross*, 776 F.3d 721 (2015), *aff'd sub nom.* *Glossip v. Gross*, No. 14-7955, 2015 WL 2473454 (U.S. June 29, 2015) (No. 14-6244).

research ethically permissible. I argue that we need not get that far if it is research: Because it lacks social value, it is unethical.

Parts II and III provide reasons to doubt the empirical claims and normative conclusions of *Experimental Execution*. Shah's normative conclusion is that the law and ethics of human subjects research should govern lethal injection reform. Empirical claims underlie that normative view. Shah argues that the capital inmate's relationship to the corrections department is sufficiently similar to the relationship between a research participant and investigator. She also claims that the application of the law and ethics of human subjects research will help ensure less suffering during executions. Part II argues against Shah's normative conclusion by providing reasons to reject its underlying empirical assumptions. Finally, Part III argues that describing lethal injection reforms as human subjects research fails to add moral or legal reasons to condemn the way in which states have conducted recent executions.

#### I. IF IT IS RESEARCH, DOES IT HAVE SOCIAL VALUE?

If Shah is correct that states are engaging in medical research, then this research is unethical. Of course, one might argue that the research is unethical because the death penalty is immoral. However, I contend that even if the death penalty is a morally permissible punishment in at least some cases, this alleged research would be unethical for the state to conduct because it fails the research ethics requirement of providing new and valuable knowledge. In other words, I argue that even if the death penalty is morally permissible, the "research" nonetheless lacks social value. Even if states adopted Shah's recommendations of requiring informed consent and IRB review, the research would still be unethical. To start, a research protocol is ethical only if that research has social value.<sup>17</sup> When research seeks to find "what is already well known" it lacks social value.<sup>18</sup> It is ethically impermissible to expose persons to medical risks—especially persons who are particularly vulnerable to coercion—if the research lacks social value.<sup>19</sup>

Regardless of whether the death penalty is morally justifiable, the

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17. Ezekiel Emanuel et al., *Research Ethics: How to Treat People Who Participate in Research*, NATL. INST. OF HEALTH 4 (2011), available at [http://www.bioethics.nih.gov/education/pdf/FNIH\\_BioethicsBrochure\\_WEB.PDF](http://www.bioethics.nih.gov/education/pdf/FNIH_BioethicsBrochure_WEB.PDF).

18. *Id.*

19. See Ezekiel Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2703 (2000).

“experimenting” in which states are engaged lacks social value. Shah asserts that the aim of the experimentation is to “improve [execution] protocols to use on other inmates on death row.”<sup>20</sup> In what way are states trying to “improve” their protocols? I do not want to attribute an answer to Shah, but one intuitive answer is the following: States are trying to find a lethal injection procedure that will terminate a life while minimizing the risk of pain and suffering. The problem, though, is that this cannot be the actual aim of the experimentation: *We already know how to kill someone without causing suffering*. Physicians perform neurosurgery, and patients feel nothing. Some states use a single overdose of a barbiturate, the same kind of drug that has been prescribed in Oregon under its Death with Dignity Act.<sup>21</sup> And even if states cannot obtain a barbiturate for single-dose executions, other means of killing quickly, minimizing the risk of prolonged suffering, exist. Surely people know that the state can render an inmate unconscious with some drug—whether it is a drug used by medical professionals or not—and then kill him by means that governments have used in the past. The state could intoxicate and anesthetize an inmate and then riddle his head with bullets, blowing up his brain and causing death in an instant. The state could render an inmate unconscious before employing the guillotine. I am sure others can think of many more such execution protocols that would kill an inmate quickly right after rendering him unconsciousness. Consider the following: The reason midazolam’s use in executions is so problematic is because potassium chloride does not kill instantaneously. The searing pain it causes is “sufficiently noxious to break through the midazolam-induced sedation.”<sup>22</sup> If the burning pain causes the inmate to regain consciousness, there is time for him to suffer intensely. Death might take up to two minutes.<sup>23</sup> Midazolam would not be a problem in terms of permitting pain if, after it causes unconsciousness, the inmate were killed instantly.

So what is the supposed aim or value of this “experimentation” if it is not to find a way to kill someone while minimizing the risk of pain?

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20. Shah, *supra* note 13, at 152.

21. *State by State Lethal Injection*, DEATH PENALTY INFORMATION CENTER, <http://www.deathpenaltyinfo.org/state-lethal-injection> (last visited June 29, 2015) (listing states using pentobarbital in a one-drug protocol); OR. DEP’T OF HUMAN SERVS., SIXTH ANNUAL REPORT ON OREGON’S DEATH WITH DIGNITY ACT 23 (2004), *available at* <https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Documents/year6.pdf>.

22. Waisel & Litton, *supra* note 4.

23. Mark Dershwitz & Thomas K. Henthorn, *The Pharmacokinetics and Pharmacodynamics of Thiopental as Used in Lethal Injection*, 35 *FORDHAM URB. L. J.* 931, 946 (2008).

Perhaps other options for killing painlessly that I mentioned (besides a barbiturate overdose) are more gruesome, and inmates themselves have an interest against such executions even if painless. I am skeptical, though, that pro-death-penalty states are motivated by a concern to protect dignity interests of condemned inmates *for the sake of the inmates*.

Rather, I suggest the following: Death penalty states want to terminate an inmate's life using only drugs because doing so makes the death penalty more palatable to others, including the public. As others have observed, "[l]ethal injection looks more like therapy than punishment."<sup>24</sup> The purpose of killing with drugs is to "mask the brutality of execution by making them look serene and peaceful—like something any one of us might experience in our final moments."<sup>25</sup> Some commentators surmise that the level of public support for the death penalty rests in part on the "medicalization" of executions.<sup>26</sup> By medicalizing executions, the state can maintain and influence public support for the death penalty.

If the state conducts human subjects research to find a means of killing that permits the state to maintain and influence public support for the death penalty, then that research is immoral. The state disrespects the public by attempting to influence public opinion by a means that has nothing to do with the *reasons* to support the death penalty. Medicalizing executions may cause people to feel more comfortable with killing; it avoids causing feelings of disgust and horror that might be caused by more graphic newspaper accounts of executions by other means. However, the fact that executions are medicalized and sanitized neither constitutes nor reveals any reasons that morally speak in favor of capital punishment. It is illegitimate for the state to try to influence public opinion in a way that bypasses reasoning.

The state may attempt to maintain or influence public opinion on an important social matter such as the death penalty. The government may "defend its own policies."<sup>27</sup> However, in a democracy, the state may not

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24. Deborah W. Denno, *When Legislators Delegate Death: The Troubling Paradox Behind State Uses of Electrocution and Lethal Injection and What It Says About Us*, 63 OHIO ST. L.J. 63 (2002) (quoting Jerome D. Gorman et al., *The Case Against Lethal Injection*, 115 VA. MED. 576, 576–77 (1988)).

25. *Wood v. Ryan*, 759 F.3d 1076, 1103 (9th Cir. 2014) (Kozinski, J., dissenting from denial of rehearing en banc).

26. See, e.g., Daniel N. Lerman, *Second Opinion: Inconsistent Deference to Medical Ethics in Death Penalty Jurisprudence*, 95 GEO. L.J. 1941, 1947 (2007).

27. *Bd. of Regents of the Univ. of Wisconsin Sys. v. Southworth*, 529 U.S. 217, 229 (2000) ("The government, as a general rule, may support valid programs and policies by taxes or other exactions

try to influence public opinion on an important matter in a way that bypasses “reasoned discussion and deliberation.”<sup>28</sup> Whether legislators and citizens support or oppose the death penalty should be based on questions about its retributive value (if any), its deterrent value (if any), and other moral, policy, and financial considerations. It is morally illegitimate for the state to manipulate public opinion by means that have nothing to do with reasons that speak for or against capital punishment. Therefore, if Shah is correct in deeming lethal injection reform to be human subjects research, then the research fails the requirements for ethical research regardless of any consent process or expert review.

## II. ARE RESEARCH ETHICS REQUIREMENTS APPLICABLE?

Shah is certainly right that the “mere fact that an inmate is sentenced to death should not suspend the standard protections to which all of us are entitled.”<sup>29</sup> The question, though, is whether good reason exists to apply the law and ethics of research to the lethal injection context. If good reason is lacking, then we are not suspending research protections to which an inmate is entitled. In this section I argue that good reason does not exist to apply research ethics requirements to lethal injection reform. The relationship between condemned inmates and corrections departments (including the execution team) is not similar for ethical purposes to the relationship between research participants and investigators. Second, the justifications for particular research ethics requirements—such as informed consent—are inapplicable in the lethal injection context.

The essence of Shah’s normative argument that the law and ethics of research should bind execution reform is the following: There are features of research that call for strong ethical and legal requirements, and those same features also exist in the execution context. First, research may involve risks of bodily harm to research subjects. Similarly, experimentation with lethal injection protocols involves risks of suffering to condemned inmates. Second, research necessarily

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binding on protesting parties. Within this broader principle it seems inevitable that funds raised by the government will be spent for speech and other expression to advocate and defend its own policies.”). My argument does not dispute the government speech doctrine, according to which the state may express its own point of view even on morally contentious issues. *Id.*

28. Tom Christiano, *Democracy*, STAN. ENCYCLOPEDIA PHIL., <http://plato.stanford.edu/entries/democracy/> (discussing Joshua Cohen’s account of democracy described in *Procedure and Substance in Deliberative Democracy*, in PHILOSOPHY AND DEMOCRACY 21 (Tom Christiano ed., 2002)).

29. Shah, *supra* note 13, at 155.



involves parties—researchers and patient-subjects—who have diverging interests. Researchers want to produce generalizable knowledge that may lead to the improvement of human welfare. They may also seek personal benefit from their work and publications, including “prestige, status, career advancement, satisfaction of curiosity, and money.”<sup>30</sup> Patient-subjects, though, are the ones who face the risks required for researchers to achieve their goals. Likewise, Shah argues, the interest of a corrections department and an inmate are not perfectly aligned.<sup>31</sup> Both have an interest in a painless execution, but the corrections department, lacking certainty about drug effects, has an interest in producing knowledge for future executions. Perhaps, though, an even more worrisome concern is that corrections departments deal with political and time pressure to change an execution method because of drug shortages or other reasons.

Shah is right that these diverging interests are cause for concern. The recent Oklahoma experience demonstrates how time and political pressure on a corrections department can lead to a terrible choice of drug.<sup>32</sup> However, the fact that condemned inmates may suffer harm and have interests in tension with corrections officials does not imply that the same ethical and legal requirements should bind the execution context.

For example, consider the informed consent requirement for medical research. Shah argues that extending the ethical requirement of informed consent to condemned inmates can or will help reduce the risks of unnecessary suffering that they face. In human subjects research, the ethical requirement of informed consent has two purposes: “to ensure that individuals control whether or not they enroll in clinical research and participate only when the research is consistent with their values, interests, and preferences.”<sup>33</sup> Shah argues that “just as some inmates might be given a choice to participate in research . . . testing a new medication for treating HIV, so too should inmates be asked for their consent to participate in *research* about how they should be killed.”<sup>34</sup> Moreover, Shah argues that requiring informed consent before enrolling an inmate in execution research will actually help the inmate protect his interests.<sup>35</sup> For example, Shah argues, an inmate with a particular

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30. *Id.* at 164.

31. *Id.*

32. Brief of Appellant, *supra* note 16, at 22–27.

33. Emanuel, *supra* note 19, at 2706.

34. Shah, *supra* note 13, at 199 (emphasis in original).

35. *See id.* at 198–202.

medical condition that increases the risk of a painful lethal injection might be able to bring his condition to bear in a decision about whether to participate in the state's protocol reform efforts.<sup>36</sup>

Shah's empirical assumption is that asking death row inmates to consent to execution research will help them protect their interests. However, if that empirical assumption is false, then the normative conclusion—that the informed consent requirement should be applied—loses its justification. In the following, I explain why I am skeptical of the empirical assumption.

First, I must admit finding something morally grotesque about the state asking an inmate, who the state is about to kill, for permission to expose the inmate to risk so that it may find the best way to kill others in the future. It is hard to imagine why an inmate would or should be disposed to helping the state in this manner. Let us first contrast an execution with the normal medical context in which a physician or researcher asks a patient to enroll in research. It is reasonable for a physician to ask a patient if she is willing to participate in research and bear risk for the good of others because perfectly intelligible reasons exist to justify a patient's agreement. For one, some patients consent to research for altruistic reasons; they want to contribute to improving human welfare. Patients can derive meaning from their illness by participating in research that will hopefully help prevent or alleviate the suffering of people in the future.<sup>37</sup> A patient might also reasonably believe that she has benefitted greatly from the advancement of medicine and therefore has a responsibility to participate in the ongoing production of medical knowledge. In addition, patients often feel good will towards their doctors, grateful for the way in which their doctors have cared for them. The context makes it quite understandable why a patient would see good reason to accept an invitation to enroll in research and take on risk for the good of others. Accordingly, some commentators have described the ideal researcher-subject relationship as a *joint venture*, in which they share in the goal of improving human welfare.<sup>38</sup>

These facts do not apply to the execution context. Execution "research" cannot be a joint venture. A condemned inmate does not have reason to be altruistic towards the state, which is killing him against his

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36. *Id.* at 200.

37. Paul Litton & Franklin G. Miller, *A Normative Justification for Distinguishing the Ethics of Clinical Research from the Ethics of Medical Care*, 33 J.L. MED. & ETHICS 566, 569 (2005).

38. *See, e.g.*, CHARLES FRIED, *MEDICAL EXPERIMENTATION: PERSONAL INTEGRITY AND SOCIAL POLICY* 172 (1974).

will, to help the state find a way to execute that sits well with the public. Again, as argued before, the state knows how to kill people quickly with little risk of pain. The purpose of this alleged research is to find ways to kill that maintain support for the death penalty. We should hope that guilty inmates attempt to repent, reform, and benefit others in ways they can. However, we should not expect that their rehabilitation include volunteering for the state's endeavor to find a more peaceful way to kill more inmates. A patient might see an obligation to help advance medicine because of the medical benefits she has received throughout her life. Inmates have no analogous obligation to the state to help it maintain the death penalty; they have not received benefits from the existence of the death penalty. Finally, unlike the normal good will within the doctor-patient relationship, the execution differs in that inmates most often lack good will towards the state. It is just unseemly of the state, before killing a person, to ask him to take on risk so that it can kill others.

Shah also supports her conclusion—that ethical and legal requirements of research should apply to execution reform—by claiming that the application of those requirements, such as informed consent, will help inmates protect their own interests and reduce their risk of suffering.<sup>39</sup> However, it is difficult to see how an informed consent requirement will help an inmate protect his interests. The context is plainly coercive. Corrections officials, asking the inmate to consent, are in control of whether he is going to suffer extreme pain during the execution. They are going to kill him one way or another. The inmate wants to make sure that the risk of pain is as low as possible. He is not sufficiently free to decline when he knows that agents acting on behalf of corrections are in control of whether he suffers or not. Executioners can deliberately cause pain, and whether or not they would, an inmate may certainly and legitimately fear such intentional infliction of pain. Consent may be informed, but, for ethical purposes, it would not be freely given.

Another obstacle to meaningful informed consent is the fact that *both* options—the “standard” or “unmodified” protocol, and the “experimental” or “modified” protocol—might be terrible. To use Shah's words, *both* can be “poorly designed and not based on evidence.”<sup>40</sup> A non-lethal injection option might even be barbaric. Shah writes: “States seeking to modify their lethal injection protocols would

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39. Shah, *supra* note 13, at 198–202.

40. *Id.* at 155.

have to ask inmates whether they prefer the modified or unmodified version of the protocol or could offer inmates a choice of a different method of execution altogether.”<sup>41</sup> That choice, according to Shah, might involve “older methods of execution to offer alternatives.”<sup>42</sup> Imagine the choice is between lethal gas—an older method of execution<sup>43</sup>—and some experimental lethal injection protocol that, say, uses midazolam as the first drug. The inmate choosing the latter is not freely giving informed consent to participate in research for the good of others. That inmate could very well choose the experimental method because of the known horrors of dying via lethal gas.<sup>44</sup> In medical research, usually one option for a patient is the standard of care, the best treatment we have, given current knowledge. Given the way states have concocted their execution protocols, there is no reason to trust that the “unmodified,” non-experimental option for execution is actually acceptable and constitutional.

The objections I have raised so far cast doubt on whether an informed consent requirement would allow inmates to actually protect their own interests and reduce the risk of a botched, painful execution. There is another obstacle, not to the inmate protecting himself, but to implementing such a requirement. Who would actually administer the informed consent process and how would it be done? The process should not be administered by a department of corrections employee who is not a medical professional. Informed consent is not merely about obtaining a research participant’s agreement; it is supposed to be a process of communication in which the potential participant learns about the nature and purpose of the research, the risks and benefits of enrolling, and the risks and benefits of alternatives to participation.<sup>45</sup> The potential participant should also have the opportunity to ask questions so that her decision may be fully informed. The federal regulations, for example, require the informed consent process to include “[a]n explanation of whom to contact for answer to pertinent questions about the research.”<sup>46</sup> Non-medical professionals cannot be the only willing administrators of

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41. *Id.* at 199.

42. *Id.* at 200.

43. MO. REV. STAT. § 546.720 (2014). (“The manner of inflicting the punishment of death shall be by the administration of lethal gas or by means of the administration of lethal injection.”).

44. See Deborah W. Denno, *The Lethal Injection Quandary: How Medicine Has Dismantled the Death Penalty*, 76 *FORDHAM L. REV.* 49, 63 (2007) (discussing Donald Harding’s horrific execution by lethal gas in Arizona).

45. Emanuel, *supra* note 19, at 2706.

46. 45 C.F.R. § 46.116(a)(7) (2014).

this process. At least one medical professional must be on hand to answer questions about this alleged research.

But would—and *should*—any physician actually participate in *this* manner in an execution? Professional medical societies, such as the American Medical Association (AMA), American Society of Anesthesiologists, and the American Nurses Association, condemn the participation of medical professionals in executions. The AMA Code of Ethics specifically condemns even consulting the execution team, which a physician who administers an informed consent process would have to do. This consensus among professional organizations is why some states, such as California,<sup>47</sup> have been unable to secure participation of physicians in their executions. Granted, some other jurisdictions have been able to employ physicians for executions.<sup>48</sup> However, would it be ethical for a physician to steward a condemned inmate through the informed consent process for purposes of enrolling him in execution research? Some commentators have defended physicians who participate in executions.<sup>49</sup> Are their arguments applicable to the current issue at hand?

Though commentators have presented reasonable arguments defending the participation of physicians in some execution procedures, their arguments would not support physician administration of an informed consent process. These commentators have challenged the ethics position of the AMA and other professional organizations by arguing that physicians can actually reduce the risk of unnecessary suffering during an execution.<sup>50</sup> A traditional function of medicine is to reduce the risk of suffering. Insofar as a physician can ensure proper delivery of a barbiturate, which would prevent excruciating pain that would otherwise be caused, a physician acts in accordance with principles of medical ethics. These arguments in favor of physician participation, though, cannot justify a physician's administration of the informed consent process through which a death row inmate is asked to participate in "execution research." If my concerns above are correct, an informed consent requirement will not effectively permit inmates to protect their own interests. As stated, the context is necessarily coercive. A physician might be able to protect an inmate's interest by ensuring

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47. Denno, *supra* note 44, at 49.

48. Atul Gawande, *When Law and Ethics Collide: Why Physicians Participate in Executions*, 354 *NEW ENG. J. MED.* 1221, 1223 (2006).

49. *See, e.g.*, David Waisel, *Physician Participation in Capital Punishment*, 82 *MAYO CLIN. PROC.* 1073 (2007).

50. *Id.*

proper delivery of the barbiturate, to make sure the inmate does not experience any suffering. However, if the execution is truly research to produce generalizable knowledge for future state-sanctioned killings, it is difficult to see how a physician's administration of an alleged informed consent process could really protect an inmate's interests.

### III. DOES CALLING IT "RESEARCH" MATTER?

Shah rightfully asserts that the lethal injection reforms implemented by states are "poorly designed and not based in evidence."<sup>51</sup> Their poor design and lack of evidentiary support are, according to Shah, causing the disturbing rate of botched executions. Shah aims to address the root of the problem: "Viewing lethal injection executions through [the lens of research ethics] can help ensure that states have a solid scientific basis and are neither excessively risky nor disrespectful of inmates on death row."<sup>52</sup>

Is the ethical problem that the protocols are "poorly designed and not based in evidence,"<sup>53</sup> or that they are "poorly designed *research*,"<sup>54</sup> inadequately supported by evidence? By calling these reforms "research," would we add either to the moral or legal reasons the state has to avoid execution methods that are "poorly designed and not based on evidence"? In this section I argue that we would not.

To begin, the state already has an extremely strong moral obligation to respect condemned prisoners as persons, regardless of their crimes; it is immoral to choose methods of punishment that are poorly designed. Even worse, it is, at the least, grossly negligent to choose a method of execution that supposedly involves administering an effective anesthetic agent when there is good scientific reason to doubt that the chosen means of anesthesia does not actually have the desired medical properties.

The state's moral obligation is based on the fact that it is inflicting punishment. Given the extreme harm the state inflicts on a prisoner, the state is morally justified only if "the end to be achieved is of undeniable importance to society, and no less severe [punishment] will suffice."<sup>55</sup>

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51. Shah, *supra* note 13, at 152.

52. *Id.* at 153.

53. *Id.* at 152.

54. *Id.* at 191 (emphasis added).

55. Hugo Adam Bedau, *An Abolitionist's Survey of the Death Penalty in America Today*, in *DEBATING THE DEATH PENALTY: SHOULD AMERICA HAVE CAPITAL PUNISHMENT?* 32 (Hugo A. Bedau & Paul G. Cassell eds., 2004).

The fact that punishment is morally justified only if it is necessary to achieve a compelling state interest—only if a less severe punishment is not adequate—is why the Supreme Court, in its death penalty proportionality cases, asks whether the challenged punishment serves a legitimate state purpose such as retributive justice or deterrence.<sup>56</sup> If a punishment is not needed to serve a state interest, it is unjustified. The infliction of severe suffering without justification is, indeed, cruel. Correspondingly, the state has a moral obligation to inflict punishment only when necessary. If state officials, by poorly designing a protocol without a scientific basis, culpably inflict torturous suffering upon an inmate that exceeds what is necessary to inflict his sentence, then such officials have grossly violated a serious moral obligation owed to affected inmates.

Categorizing the lethal injection reform as “research” just does not add to our moral reasons to condemn the state for using execution methods so hastily and unjustifiably chosen. Shah’s position reminds me of Joseph Raz’s question of whether a moral obligation to obey law adds to an individual’s moral reasons to refrain from committing murder or other violent crime.<sup>57</sup> The fact that the law punishes such crimes provides self-interested reasons to refrain; but does the law add to our *moral* obligation to refrain? Given the weight of our moral obligation to refrain from committing murder, any alleged moral obligation to obey the law adds no weight to our moral obligation to refrain from violence.<sup>58</sup> Analogous to the present context, the question is whether calling the changes to lethal injection protocols “research” adds anything to the state’s moral obligations to avoid “poorly designed” execution procedures that are not based on science. Given the weight of the state’s obligation to avoid the infliction of unnecessary suffering through poorly designed *punishment*, an alleged duty to avoid poorly designed *research* adds very little to the state’s moral obligations in this context.

Shah contends, though, that the law governing research is also applicable, in addition to research ethics.<sup>59</sup> The law of research, like research ethics, requires risk minimization.<sup>60</sup> Shah argues that the

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56. See, e.g., *Kennedy v. Louisiana*, 554 U.S. 407 (2008); *Roper v. Simmons*, 543 U.S. 551 (2005); *Atkins v. Virginia*, 536 U.S. 304 (2002).

57. See Joseph Raz, *The Obligation To Obey: Revision and Tradition*, 1 NOTRE DAME J.L. ETHICS & PUB. POL’Y 139 (1984).

58. *Id.* at 140–41.

59. Shah, *supra* note 13 at 157.

60. See, e.g., 45 C.F.R. § 46.111(a) (2014) (“In order to approve research covered by this policy the IRB shall determine that . . . (1) [r]isks to subjects are minimized . . .”).

Court's Eighth Amendment jurisprudence is not as protective as regulations that govern research. Chief Justice Roberts's plurality opinion in *Baze* does not require risk minimization. An execution protocol can fail to minimize risks yet, simultaneously, pass *Baze*'s standard by presenting less than a "substantial risk of serious harm."<sup>61</sup> Shah argues, "Justice Ginsburg's dissent requiring that there be no 'untoward risk' was the only standard that was consistent with the obligation to minimize risks in research or quality control activities."<sup>62</sup>

Is there a practical difference among a prohibition on "substantial risk[s] of serious harm," a prohibition on "untoward risk[s]," and a requirement that risks be minimized? On their face, I agree with Shah that they differ. On the other hand, we have reason to wonder whether, or how often, a decisionmaker disposed to seeing an "untoward" risk of harm would deny the existence of a "substantial risk of serious harm," particularly in the execution context. In attempts to apply these standards, how often would the same decisionmaker conclude that an execution protocol fails to minimize risks yet simultaneously find no substantial risk of serious harm? The same decisionmaker might be prone to seeing a "substantial risk of serious harm" in the same case she concludes that the state has failed to minimize the risks involved in an execution.

In fact, consider Shah's own application of the *Baze* plurality standard in the following passage. It suggests that Shah sees current lethal injection experimentation as not only failing the research requirement to minimize risk, but also as violating the more permissive standard from the *Baze* plurality:

Importantly, the plurality opinion in *Baze* indicated that a lethal injection protocol would violate the Eighth Amendment if it involves a "substantial risk of serious harm" or an "objectively intolerable risk of harm," and there are alternative execution methods that effectively address this risk." When faced with examples of problematic executions, the Court opined that "an isolated mishap," or an "accident, with no suggestion of malevolence" would not be enough to sustain a challenge based on the Eighth Amendment. *Yet, states are increasingly engaged in experimentation that disregards many potential risks and the considerable uncertainty as to whether procedures will work as planned. Given the growing number of examples of executions gone wrong, it is difficult to believe that these failures are*

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61. *Baze v. Rees*, 553 U.S. 35, 52 (2008).

62. Shah, *supra* note 13, at 196. (citing *Baze*, 553 U.S. at 123 (Ginsburg, J., dissenting)).



*merely a series of accidents*. Rather, the problem is systemic and foreseeable. Poorly regulated and haphazard experimentation on inmates predictably leads to bad outcomes.<sup>63</sup>

“Given the growing number of examples of executions gone wrong,” we should not view the terrible outcomes as “isolated mishap[s]” or “accident[s], with no suggestion of malevolence.” Perhaps the malevolence is not equated with purposeful infliction of suffering, but recklessness and indifference can be malevolent, particularly in this context.

Finally, if the *Baze* standard is not strong enough to prohibit “poorly designed” protocols that are “not based on evidence,” then there is a problem with the *Baze* standard. There is no justification for the state to execute death row inmates with recklessly chosen procedures. Reckless or grossly negligent infliction of torturous suffering has no justification, and, as such, is cruel. States have a constitutional obligation to avoid cruel and unusual punishments. The Constitution already forbids the reckless and grossly negligent infliction of torturous suffering, whether it is inflicted through means that look like medical research or not. Therefore, labeling recent reforms as “research” seems to add little to the state’s legal reasons to avoid “poorly designed” protocols “not based on evidence.”

## CONCLUSION

Shah’s goal is admirable. Finding recent reforms to count as research, she argues that some kind of independent oversight is required to prevent states from employing poorly designed execution methods in their quest to kill the very few offenders who are sentenced to death. As explained, I am not persuaded that her creative suggestion is the solution. The relationship between death row inmates and corrections officials is not analogous, from an ethical perspective, to the research subject-investigator relationship. Moreover, the legal and ethics requirement of informed consent for research will not help inmates protect their interests. These two facts are reasons why the law and ethics of human subjects research is not applicable to lethal injection reform. Nonetheless, states have weighty ethical and legal obligations to cease employing poor means of execution. Terribly designed protocols have no justification.

Shah and I join the call for rationality in the search for a humane

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63. *Id.* at 153 (emphasis added) (citations omitted).

method of killing. I do, however, readily admit that such a call is, perhaps, hopeless and odd. Death penalty states seem unwilling even to assess whether having capital punishment is rational. In my own state of Missouri, a senate committee annually refuses to bring to the floor a bill that would simply require the state auditor to calculate the financial cost of the death penalty to the state.<sup>64</sup> Politicians do not want to know whether there are any reasons to abolish the death penalty. Hopefully recent botched executions will cause states not only to reexamine their protocols, but to have the courage to assess whether this punishment, which constitutes such a small part of the criminal justice system, is actually worth its trouble and cost.

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64. Press Release: Sen. Keaveny Files Legislation Examining Coasts of Administering Death Penalty in Missouri, THE MISSOURI TIMES BLOG (Jan. 14, 2015), <http://themissouritimes.com/15885/press-release-sen-keaveny-files-legislation-examining-costs-administering-death-penalty-missouri/>. The most recent bill did not pass out of the Governmental Accountability and Fiscal Oversight Committee despite bipartisan sponsorship. *MO SB240*, BILLTRACK50, <https://www.billtrack50.com/BillDetail/543125> (last visited June 29, 2015).