

## WHY HAVE IRBS AT ALL?

A REPLY TO NOAH

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### INTRODUCTION

In *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*,<sup>1</sup> Professor Lars Noah raises a number of objections to my analysis of the role of institutional review boards (IRBs) in our system of human subject protection, as well as to my suggestions for procedural mechanisms to promote a more reasoned and transparent process of IRB review.<sup>2</sup> His article is, to some extent, more sweeping than mine, in that he rebuts arguments that I not only did not make in my article, but that I quite explicitly rejected.<sup>3</sup> On those issues, of course, I find his article extremely persuasive.

More importantly, he and I simply disagree about certain fundamental issues related to both the IRB system and the usefulness of procedural requirements more generally. For example, where he sees IRBs as a largely redundant mechanism for providing “another ‘gut check’” on the acceptability of research,<sup>4</sup> I regard them as a critical safeguard in a system often otherwise devoid of effective control. In addition, while Noah obviously has little patience for procedural constraints on IRBs’ ability to make discretionary decisions, I see such constraints as vital to both the quality of the decision-making process and the legitimacy of the system of human subject protection overall.

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<sup>1</sup> Lars Noah, *Deputizing Institutional Review Boards to Police (Audit?) Biomedical Research*, 25 J. LEGAL MED. 267 (2004).

<sup>2</sup> See Carl H. Coleman, *Rationalizing Risk Assessment in Human Subject Research*, 46 ARIZ. L. REV. 1 (2004).

<sup>3</sup> See *infra* text accompanying notes 5-16.

<sup>4</sup> Noah, *supra* note 1, at 272.

## I. MISUNDERSTANDINGS

Before discussing the differing perspectives that underlie Noah's and my positions, I feel compelled to point out at least a few of the ways that Noah's response to my article rests on a misunderstanding of some basic points. First, many of Noah's criticisms are based on the premise that my proposed reforms would transform IRBs into "adversarial dispute resolution bodies."<sup>5</sup> In fact, much of my article is devoted to explaining why the adversarial dispute resolution system is *not* the appropriate model for structuring the process of IRB review.<sup>6</sup> It is true that I call on IRBs to incorporate certain features of common law judicial reasoning, but incorporating such mechanisms would not automatically transform IRBs into "miniature appellate courts."<sup>7</sup> The primary feature of judicial decision-making that I emphasize in my article—the process of reasoning by analogy—is by no means an exclusively "judicial" activity; on the contrary, it is a common analytical method used by ordinary people making decisions every day.<sup>8</sup>

The same is true for my suggestions for written reasons in support of a particular decision or seeking review of difficult decisions by individuals at a higher level of authority. These techniques facilitate decision-making in a wide range of areas of human activity, ranging from business affairs to family relations. The point of incorporating these mechanisms into IRBs' decision-making would be to give structure to the overly impressionistic and case-by-case deliberations that characterize the current process, not to turn IRBs into quasi-judicial forums in which opposing "parties" argue different "sides" of a case.

Second, Noah apparently believes that rationalizing IRB decision-making makes sense only if one assumes that federal agencies have "delegated full regulatory powers to IRBs,"<sup>9</sup> and he therefore interprets my statement about the legal source of IRBs' authority as reflecting a mistaken understanding of the relationship between IRBs and administrative agencies. However, I never suggested that IRBs constitute state actors, nor did I dispute Noah's observation that IRBs' exercise of "quasi-regulatory functions" is a relatively common feature of the modern administrative state.<sup>10</sup> The premise of my article was simply that IRBs are engaged in the process of interpreting and enforcing legal requirements pursuant to authority that has been granted to

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<sup>5</sup> *Id.* at 280.

<sup>6</sup> *See, e.g.*, Coleman, *supra* note 2, at 24-26 (arguing that the existing similarities between IRBs and juries are inappropriate because IRBs are not engaged in the retrospective resolution of disputes).

<sup>7</sup> Noah, *supra* note 1, at 273.

<sup>8</sup> *See, e.g.*, Carson Strong, *Justification in Ethics*, in *MORAL THEORY AND MORAL JUDGMENTS IN MEDICAL ETHICS* 193 (Baruch A. Brody ed. 1988) (explaining how considering "paradigm cases" can suggest how to balance competing considerations in new situations).

<sup>9</sup> Noah, *supra* note 1, at 277.

<sup>10</sup> *Id.* at 278.

them by federal regulations.<sup>11</sup> I emphasized this point because it demonstrates that IRBs' decisions have a significant impact on biomedical research (far greater than, for example, decisions by a merely advisory body), and because it shows that the success of the IRB system directly reflects on the effectiveness of the overall federal regulatory scheme. These factors amply justify concerns about the rationality and legitimacy of the IRB system, even though IRBs quite obviously are not governmental regulators exercising "the full panoply of powers vested in the FDA or HHS."<sup>12</sup>

Finally, Noah suggests that the goal of my proposed reforms is to ensure that IRBs reach consistent positions on matters with "multiple plausible answers,"<sup>13</sup> a goal he rightly points out would be both unattainable and unwise. Yet, while I emphasized the benefits of mechanisms to decrease arbitrary inconsistency in IRB decision-making, I explicitly stressed that "it is not necessarily inappropriate for different decision-makers to react differently to comparable situations," especially on matters that involve "opinions rather than objectively determinable facts."<sup>14</sup> Instead, my proposed reforms seek to ensure that, when an IRB departs from an approach that another IRB has previously taken, it does so after recognizing its deviation from a prior position and considering whether the resulting inconsistency is justified under the circumstances.<sup>15</sup> There is a world of difference between a fully informed and considered difference of opinion on a controversial issue and inconsistencies that stem from "nonsubstantive factors like varying access to information, differences in how information is presented, or the diversity of perspectives incorporated into the deliberative process."<sup>16</sup>

## II. DIFFERING PERSPECTIVES

Although some of Noah's objections can be attributed to these and other misunderstandings of certain aspects of my argument, much of his disagreement simply reflects the fact that he and I approach these issues from fundamentally different points of view. Perhaps our most basic disagreement relates to the importance of IRBs in the overall system of human subject protection. According to Noah, I have exaggerated IRBs' importance and failed to recognize that "IRBs do not represent the only game in town."<sup>17</sup> He points

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<sup>11</sup> Coleman, *supra* note 2, at 4 ("IRBs are engaged in a process of *legal* decision-making, insofar as they are interpreting specific regulatory requirements pursuant to authority that has been delegated to them by administrative agencies.") (emphasis in original).

<sup>12</sup> Noah, *supra* note 1, at 279.

<sup>13</sup> *Id.* at 280.

<sup>14</sup> Coleman, *supra* note 2, at 23.

<sup>15</sup> *See id.* at 38 (emphasizing the importance of distinguishing between analogical reasoning and "the rote application of precedent").

<sup>16</sup> *Id.* at 24.

<sup>17</sup> Noah, *supra* note 1, at 273.

out, for example, that the FDA must initially clear all research involving unapproved drugs, as well as research involving unapproved medical devices that pose significant risks.<sup>18</sup> In addition, he maintains that continuing agency oversight during the process of research, the threat of tort liability imposed on researchers or research institutions, and the unwillingness of medical journals to publish studies involving ethical improprieties together make IRBs “only one of several layers of protection against unethical and potentially dangerous research on human subjects.”<sup>19</sup>

While Noah, of course, is correct that IRBs are not the only institutions concerned with human subject protection, his confidence in the ability of these other institutions to prevent unjustifiably risky research is unsupported by the facts. First, not all research is subject to prior scrutiny at the federal level; for example, prior FDA scrutiny often is not required in studies involving the use of already-approved drugs.<sup>20</sup> Second, even when prior review of studies by the FDA or HHS takes place, it is difficult to have faith in these agencies’ ability to screen out unjustifiably risky research, given the number of recent scandals in which research subjects have experienced unjustifiable harm.<sup>21</sup> Third, as even Noah concedes, continuing agency oversight is limited to “spot check[s] . . . for adherence to general procedural requirements,”<sup>22</sup> and the deterrent effect of tort liability for human subject protection violations appears to be weak.<sup>23</sup> Finally, while it is admirable that medical journals have begun to focus on compliance with human subject protections, simply requiring researchers to “state whether they have abided by the ethical strictures found in the Declaration of Helsinki”<sup>24</sup> is a formality unlikely to have much actual effect.

While much of Noah’s article emphasizes the importance of self-regulation by the research community, he acknowledges that “the historical

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<sup>18</sup> *Id.* at 274.

<sup>19</sup> *Id.* at 273.

<sup>20</sup> See CYNTHIA MCGUIRE DUNN & GARY CHADWICK, *PROTECTING STUDY VOLUNTEERS IN RESEARCH: A MANUAL FOR INVESTIGATIVE SITES* 58 (1999) (noting that the FDA exempts clinical studies that are conducted according to a drug’s approved labeling from the requirement of obtaining an investigational new drug exemption).

<sup>21</sup> See, e.g., Coleman, *supra* note 2, at 2 (describing two healthy young women who died while participating in biomedical research).

<sup>22</sup> Noah, *supra* note 1, at 274.

<sup>23</sup> *Id.* at 275. Noah takes issue with my suggestion that difficulties proving causation are one reason for the limited role of tort liability in medical research; he claims that, “[b]y that logic, we also should dismiss any deterrent function for medical malpractice liability.” *Id.* Yet, in the very next sentence he proceeds to do just that. See *id.* (“[G]ood reasons exist to question [a deterrent] role for tort law in the context of either research or treatment.”). The reasons for the limited deterrent effect of tort law in both medical treatment and research are complex, but difficulties proving causation undoubtedly play a significant role, particularly for patients whose conditions are likely to worsen regardless of the treatment they receive.

<sup>24</sup> See *id.* at 275 n.39. (citing Int’l Comm. of Med. Journal Editors, *Uniform Requirements for Manuscripts Submitted to Biomedical Journals*, 277 J.A.M.A. 927, 929 (1997)).

record—including some widely publicized recent mishaps” makes it difficult to rely on researchers’ “sense to design clinical trials in ways that minimize the risk of injury to subjects and maximize the likely benefits to society.”<sup>25</sup> Ultimately, I cannot help but wonder whether Noah actually believes that IRBs are simply one of many players in a generally satisfactory system, or he just doubts that any system can prevent unreasonably risky research from being carried out. Yet, whatever the explanation, he is content for IRBs to remain “just one of many imperfect quality controls used in medicine,”<sup>26</sup> a perspective that I believe explains much of his opposition to my suggested procedural reforms.

Another basis of his opposition to my proposed mechanisms for reforming IRBs’ method of reviewing protocols is his sense that, as a general matter, procedural requirements often do more harm than good. It is certainly true that some administrative mechanisms have not worked particularly well, including Noah’s example of the federal disability benefits program.<sup>27</sup> Yet, the procedural mechanisms proposed in my article do not seek in the slightest to replicate the system of adjudication used in disability benefits determinations; my reference to administrative adjudications was simply to provide an example of a system that requires decision-makers to explain when they deviate from how an issue was treated in the past.<sup>28</sup> Who could disagree with the Supreme Court’s observation that “[t]he judicial model of an evidentiary hearing is neither a required, nor even the most effective, method of decisionmaking in all circumstances”?<sup>29</sup> Again, Noah’s lengthy discussion of the dangers of transforming IRBs into highly proceduralized adversarial bodies responds to an argument that my article does not make.

Noah also suggests that adding greater procedural requirements for IRB deliberations may backfire by interfering with the integrity of IRBs’ decision-making process. For example, he argues that the unreviewable discretion granted to IRBs protects human subjects by preventing research institutions from overriding an IRB’s rejection of a protocol.<sup>30</sup> All that demonstrates, however, is the danger of empowering research institutions to second-guess IRBs’ determinations, given the institutions’ vested interest in whether a particular proposal is accepted or denied. It in no way undercuts the potential benefits of appellate oversight by regional or national committees, who would have no particular stake in whether a specific study proceeds. Noah’s concern that only dissatisfied researchers would ever have an incentive to appeal a decision<sup>31</sup> is

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<sup>25</sup> *Id.* at 274.

<sup>26</sup> *Id.* at 282.

<sup>27</sup> *See id.* at 280-81.

<sup>28</sup> *See* Coleman, *supra* note 2, at 41.

<sup>29</sup> *Matthews v. Eldridge*, 424 U.S. 319, 348 (1976).

<sup>30</sup> *See* Noah, *supra* note 1, at 272.

<sup>31</sup> *See id.* at 287.

legitimate, but my article offers several suggestions for facilitating review of IRB decisions to approve protocols, suggestions that Noah simply dismisses out of hand without any analysis at all.<sup>32</sup>

In some cases, Noah seems to recognize the potential benefits of certain procedural mechanisms, such as developing procedures to facilitate comparisons to prior decisions made by IRBs at the same or different institutions or to encourage IRBs to provide written reasons for their decisions. Greater exchange of information about how different IRBs approach particular issues, he writes, would mean that “each IRB would not have to reinvent the wheel when it encounters a difficulty that has arisen elsewhere previously,”<sup>33</sup> while an “obligation to spell out on paper and then defend a decision to proceed with a particular experiment involving human subjects undoubtedly would promote reflection.”<sup>34</sup> Yet, Noah believes that these goals are already adequately accommodated in the current system, through informal exchanges at conferences, in professional journals, and online.

This assumption may reflect Noah’s academic interest in issues related to biomedical research, which leads him to assume that IRB members would naturally take an active interest in attending conferences, reading journals, and participating in online discussions. Although that is undoubtedly true for some IRB members, particularly those with an academic interest in the field of human subject protection, most members find simply preparing for and attending IRB meetings enough of a commitment of time and energy. At the risk of again providing “an exemplar of the pitfalls associated with unsophisticated analogical reasoning,”<sup>35</sup> it is instructive to compare IRB membership with service on other academic committees, such as a law school’s curriculum committee. With resources like the *Journal of Legal Education*, conferences hosted by the Association of American Law Schools, and numerous online discussion forums devoted to curricular matters in legal education, one might wonder how any member of a law school curriculum committee could come to a meeting uninformed about how other law schools approach particular curricular matters. In reality, however, a few committee members do keep up with such developments, but committee service is not a priority for most academicians. Procedures to facilitate the dissemination of information to committee members therefore can serve an important function, even assuming that some of this information is already available for the unusually motivated committee member who has the time and inclination to seek it out.<sup>36</sup>

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<sup>32</sup> See *id.* at n.102.

<sup>33</sup> *Id.* at 283.

<sup>34</sup> *Id.* at 286.

<sup>35</sup> *Id.* at 268.

<sup>36</sup> To avoid any possible misinterpretation, let me emphasize that I am not suggesting that the type of procedural mechanisms I recommend for IRBs be adopted for law school curriculum committees.

## CONCLUSION

Obviously, there is no single correct approach to designing an effective system of human subject protection; if one existed, we probably would have discovered it already. Although I believe that the procedural mechanisms proposed in my article would promote more informed and careful decision-making, I also recognize that they would be expensive to implement and that their benefits may not turn out to be worth the cost. Yet, it seems clear that some significant changes must be made to our system of human subject protection, because the current system has proven so incapable of preventing unjustifiably risky research from taking place. I therefore am particularly struck by the inadequacy of Noah's primary alternative to my proposals—to encourage IRBs “to inculcate a commitment to ethical behavior” among researchers and research institutions.<sup>37</sup> This sort of vague directive to “do good and avoid evil” is so devoid of content that it provides no useful guidance for those genuinely concerned with protecting human subjects from unjustifiable risks. Whatever one's views on the merits of adopting greater procedural requirements for IRB deliberations, it is time to move beyond vague commonplaces about the importance of ethical conduct and focus on developing concrete recommendations for protecting human subjects from research-related harms.

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<sup>37</sup> Noah, *supra* note 1, at 291.