



# Just compensation: a no-fault proposal for research-related injuries

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## ABSTRACT

Biomedical research, no matter how well designed and ethically conducted, carries uncertainties and exposes participants to risk of injury. Research injuries can range from the relatively minor to those that result in hospitalization, permanent disability, or even death. Participants might also suffer a range of economic harms related to their injuries. Unlike the vast majority of developed countries, which have implemented no-fault compensation systems, the United States continues to rely on the tort system to compensate injured research participants—an approach that is no longer morally defensible. Despite decades of US advisory panels advocating for no-fault compensation, little progress has been made. Accordingly, this article proposes a novel and necessary no-fault compensation system, grounded in the ethical notion of compensatory justice. This first-of-its-kind concrete proposal aims to treat like cases alike, offer fair compensation, and disburse

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compensation with maximum efficiency and minimum administrative cost. It also harmonizes national and international approaches—an increasingly important goal as research becomes more globalized, multi-site trials grow in number, and institutions and sponsors in the United States move to single-IRB review.

**KEYWORDS:** clinical trial, compensation, compensatory justice, no-fault compensation, research injury, remedy

Biomedical research involving human participants serves an essential and irreplaceable function in our society. It is responsible for some of the most significant medical breakthroughs of the last century,<sup>1</sup> and the knowledge it yields ensures the safety and efficacy of new drugs and devices. Reaping these societal rewards, however, is not a risk-free venture. Because sound science requires experiments grounded in uncertainty, research inherently exposes participants to a variety of potential, and often unanticipated, harms for the benefit of others. Although most harms from experimental interventions are relatively minor, research participants can sustain injuries that result in hospitalization, permanent disability, or even death.<sup>2</sup> Research participants may also suffer economic harms related to their injuries, including lost wages, work-related disability, and costs for long-term medical care.<sup>3</sup>

Despite extensive federal regulations aimed at protecting participants in research—including requirements for informed consent, risk minimization, equitable subject selection, adequate data monitoring, and institutional review board (IRB) review of proposed research<sup>4</sup>—there is no legal requirement to care for or financially compensate participants who suffer research-related injuries.<sup>5</sup> Unlike the vast majority of developed countries, which have implemented no-fault compensation systems to ensure the

<sup>1</sup> The development of antibiotics, medications for cardiovascular disease, and improved treatment for some cancers have led to a steady decline in the US mortality since 1935. Donna L. Hoyert, *Nat'l Center for Health Statistics, NCHS Data Brief No. 88, 75 Years of Mortality in the United States, 1935–2010*, at 2 (2012), <http://www.cdc.gov/nchs/data/databriefs/db88.pdf> (last accessed July 28, 2015). Biomedical research has also produced vaccines that have either eradicated or significantly mitigated diseases including smallpox, yellow fever, polio, diphtheria, tetanus, and pertussis. See Centers for Disease Control & Prevention, *Epidemiology and Prevention of Vaccine-Preventable Diseases*, Appendix E. Hamborsky J, Kroger A, Wolfe S, eds. 13th ed. Washington D.C. Public Health Foundation, 2015.

<sup>2</sup> See eg Ganesh Suntharalingam et al., *Cytokine Storm in a Phase 1 Trial of the Anti-CD28 Monoclonal Antibody TGN1412*, 355 *NEW ENG. J. MED.* 1018 (2006) (reviewing a phase 1 clinical trial that resulted in organ failure and intensive medical care for the six healthy volunteers who received the novel drug); Susan Levine, *Clinical Trial Was Near-Death Experience Worth His While*, *L.A. TIMES*, Aug. 13, 2001, at S5 (describing how five of the ten participants in a National Institutes of Health (NIH) study of an experimental hepatitis B drug died of unforeseen toxicity in 1993, and comparing that trial to a Johns Hopkins asthma study in which a healthy volunteer died in 2001); National Bioethics Advisory Commission (NBAC), *ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS, VOL. 1: REPORT AND RECOMMENDATIONS OF THE NATIONAL BIOETHICS ADVISORY COMMISSION 2–4* (2001) [hereinafter *ETHICAL AND POLICY ISSUES*] (discussing several trials in which research participants were critically injured, including the 1999 gene transfer study at the University of Pennsylvania, which resulted in the death of Jesse Gelsinger).

<sup>3</sup> Institute of Medicine, *Responsible Research: A Systems Approach to Protecting Research Participants 193–194* (2002) [hereinafter *Responsible Research*].

<sup>4</sup> 45 C.F.R. § 46.111 (2013).

<sup>5</sup> Under the status quo, injured research participants may receive acute medical care for their injuries, but very few institutions provide that care at no cost to the participant. See *infra* notes 20, 21.

provision of medical care and compensation for injured research participants,<sup>6</sup> the United States continues to rely on the tort system as the primary route to remediation.<sup>7</sup> Unfortunately, for most injured research participants, the tort system is a litigation lottery: a few plaintiffs receive large settlements, but most recover little or nothing from the legal process.<sup>8</sup> To compound this problem, a variety of federal laws preclude some classes of research participants, including international participants and the US participants in federally conducted research, from successfully bringing suit for their research-related injuries.<sup>9</sup> The absence of a federal policy to address research-related injuries means that many injured research participants are abandoned at their most vulnerable moment by the very regulations designed to protect them.<sup>10</sup>

This issue has not gone unnoticed; over the past 40 years, a number of proposals have been put forth to address the problem of compensation for research-related injuries.<sup>11</sup> Of these, the three systems that have garnered the most attention from federal advisory committees considering the issue are as follows: the creation of a specialty court (like the Vaccine Court operated under the National Vaccine Injury Compensation Program), the establishment of a nationwide compensation fund (like the September 11th Victim Compensation Fund or BP Deepwater Horizon Compensation Fund), and the enactment of a legal requirement compelling research institutions and/or research sponsors to purchase insurance or self-insure against research participants' injuries (somewhat like workers' compensation).<sup>12</sup> These proposals—as previously articulated by their proponents—have been criticized for a variety of reasons, including that they do not provide a cohesive ethical justification for compensation, do not provide a framework for evaluating claims, and require too much bureaucracy.<sup>13</sup>

This article is the first to propose a concrete and detailed no-fault compensation system, grounded in the ethical notion of compensatory justice, to address research-related injuries. Taking its cue from the 1982 President's Commission for the Study of Ethical Problems in Medicine and Biomedical Behavioral Research—which concluded that a successful compensation system would treat like cases alike, make fair payment for the harm sought to be remedied, and disburse funds with maximum efficiency

<sup>6</sup> PRESIDENTIAL COMMISSION FOR THE STUDY OF BIOETHICAL ISSUES, *MORAL SCIENCE: PROTECTING PARTICIPANTS IN HUMAN SUBJECTS RESEARCH* 57, 186–90 (2011) [hereinafter *MORAL SCIENCE*].

<sup>7</sup> Elizabeth R. Pike, *Recovering from Research: A No-Fault Proposal to Compensate Injured Research Participants*, 38 AM. J. L. & MED. 7, 23, 29 (2012).

<sup>8</sup> See *Responsible Research*, *supra* note 3, at 190, 191; see also Jeffrey O'Connell, *Tort Versus No-Fault: Compensation and Injury Prevention*, 1 ACCIDENT ANALYSIS & PREVENTION 63, 63 (1987) (invoking the phrase 'litigation lottery' to describe the tort outcomes that displace fair and rational methods of compensation).

<sup>9</sup> See Pike, *supra* note 7, at 29, 38; Elizabeth R. Pike, *In Need of Remedy: US Policy for Compensating Injured Research Participants*, 40 J. MED. ETHICS 182 (2014).

<sup>10</sup> See Leslie M. Henry, *Moral Gridlock: Conceptual Barriers to No-Fault Compensation for Injured Research Subjects*, 41 J. L. MED. & ETHICS 411, 411 (2013).

<sup>11</sup> *Id.* at 413, 421. See also Hazel Beh, *Compensation for Research Injuries*, IRB: ETHICS & HUMAN RES., May–June 2005, at 11, 13 (discussing a variety of compensation schemes including a specialty court and a nationwide compensation fund).

<sup>12</sup> *MORAL SCIENCE*, *supra* note 6, at 56, 69; *Ethical and Policy Issues*, *supra* note 2, at 123, 126.

<sup>13</sup> See Henry, *supra* note 10 (describing the absence of a cohesive justification for no-fault compensation); Pike, *supra* note 7 (critiquing the specialty court and compensation fund approaches to compensation for research-related injuries).

and minimum administrative cost<sup>14</sup>—this article argues that a no-fault compensation system should take the form of a self-governed insurance/self-insurance program, rather than a specialty court or nationwide compensation fund. The proposal requires research sponsors and institutions to self-insure or purchase insurance to cover the costs of acute medical care and compensation for injured research participants.<sup>15</sup> In addition to satisfying the criteria for an ethical compensation system set forth by the 1982 Commission, this proposal also has the benefit of harmonizing national and international approaches to compensation, an increasingly important goal as research becomes ever more globalized, as multisite trials increase in number, as the United States moves to single-IRB review, and as the most recent iteration of the Declaration of Helsinki makes compensation for research-related injury an essential component of ethical research.<sup>16</sup>

Before detailing the proposed compensation plan, this article sets forth three critical aspects of the groundwork on which it is built. First, the article starts by briefly describing the current ad hoc approach to addressing research-related injuries and explains why continuing that practice is not only practically infeasible, but also morally deficient. It then offers possible explanations for why stakeholders—including the United States government, institutions, and industry sponsors—have thus far failed to implement a no-fault compensation system despite four decades of federal advisory panels calling for such a solution. Second, the article advances a theory of compensatory justice to support the position that compensation is owed to participants who suffer research-related injuries. This theory ultimately shapes determinations about when research participants are eligible for compensation and what kinds of compensation are available. Third, the article provides a brief explanation of why the proposed no-fault insurance/self-insurance plan that follows is ethically, legally, and practically preferable to a specialty court or nationwide compensation fund.

## INADEQUACIES OF THE STATUS QUO

### Uneven Coverage for Research-Related Injuries

Under the current federal regulations, researchers, institutions, and sponsors are not required to provide free medical care or compensation to injured research participants. The human subjects research regulations simply require that, for research involving greater than minimal risk, the informed consent document must include ‘an explanation as to whether any compensation and ... any medical treatments are available if injury occurs, and if so, what they consist of, or where further information can be obtained’.<sup>17</sup> In addition, the rules stipulate that the informed consent process

<sup>14</sup> U.S. PRESIDENT’S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, COMPENSATING FOR RESEARCH INJURIES: THE ETHICAL AND LEGAL IMPLICATIONS OF PROGRAMS TO REDRESS INJURED SUBJECTS, VOL. 1, at 127 (1982) [hereinafter COMPENSATING FOR RESEARCH INJURIES].

<sup>15</sup> In this article, the term *compensation* is used to describe the *monetary* remedy that injured research participants (or their families, in the case of death) may receive. A comprehensive no-fault system should provide acute medical care at no cost to the injured participant, but when that is not feasible (eg the research site is not equipped to provide emergency care), compensation should include reimbursement for the costs of acute medical care. Compensation may also cover lost wages, disability, long-term care costs, and death benefits.

<sup>16</sup> WORLD MEDICAL ASS’N, Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects § 15 (as amended 2013).

<sup>17</sup> 45 C.F.R. § 46.116(a)(6) (2013); 21 C.F.R. § 50.25(a)(6) (2014).

cannot include any exculpatory language that would force a research participant to waive any legal right or release any investigator, sponsor, or institution from liability for negligence.<sup>18</sup>

In the absence of a legal requirement to provide care or compensation to injured participants, most academic institutions and government agencies have not implemented a compensation system.<sup>19</sup> A recent study found that more than half of the US research institutions surveyed do not offer free medical care or other compensation for research-related injuries, and that less than 5 per cent offer 'unconditional compensation', defined in that study as a statement by the research institution that it will pay for harmful effects or injuries resulting from the experimental intervention.<sup>20</sup> These findings are consistent with earlier surveys, which found that the majority of research institutions charge injured research participants the usual and customary fees for medical care and do not provide compensation for lost wages, disability, or long-term care.<sup>21</sup>

Although most academic institutions and government agencies do not cover the medical costs associated with research-related injuries, there are a few exceptions. Of these, the best-known academic institution is the University of Washington (UW), which has a self-funded, no-fault plan that provides up to \$250,000 in medical treatment at a UW facility and up to \$10,000 in out-of-pocket expenses to healthy participants who experience research-related injuries.<sup>22</sup> A handful of other academic institutions have implemented more modest self-insurance programs to provide limited

<sup>18</sup> 45 C.F.R. § 46.116 (2013); 21 C.F.R. § 50.20 (2014). To meet the conditions set forth by these two requirements, the Office for Human Research Protections (OHRP) recommends that where no care or compensation will be provided to injured research participants, the informed consent document should say the following: 'The hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge'. 'Exculpatory Language' in *Informed Consent*, OFFICE FOR HUMAN RESEARCH PROTECTIONS, Nov. 15, 1996, <http://www.hhs.gov/ohrp/policy/exculp.html> (last accessed July 28, 2015). The OHRP released proposed revisions to this guidance document in 2011, see *Draft Guidance on Exculpatory Language in Informed Consent*, OFFICE FOR HUMAN RESEARCH PROTECTIONS AND THE FOOD AND DRUG ADMINISTRATION, Aug. 19, 2011, [http://www.hhs.gov/ohrp/newsroom/rfc/exculpatorydraft2011.html#\\_ftn4](http://www.hhs.gov/ohrp/newsroom/rfc/exculpatorydraft2011.html#_ftn4) (last accessed July 28, 2015), but a new policy has not been adopted.

<sup>19</sup> David B. Resnik, *Compensation for Research-Related Injuries: Ethical and Legal Issues*, 27 J. LEGAL MED. 263, 273–79 (2006) (quoting the language that addresses compensation for research-related injuries from several institution's informed consent documents).

<sup>20</sup> David B. Resnik et al., *Research-Related Injury Compensation Policies of U.S. Research Institutions*, 36 IRB: ETHICS & HUMAN RES. 12 (2014).

<sup>21</sup> See LEWIN GROUP, FINAL REPORT: TASK ORDER NO. 2: CARE/COMPENSATION FOR INJURIES IN CLINICAL RESEARCH (2005) (reviewing policies from 129 institutions and finding that none offered compensation for lost wages, disability, or pain and suffering, and only 11 offered to provide free care or treatment for research-related injuries, while the majority charged injured research participants the usual and customary fees for medical care); Michael K. Paasche-Orlow & Frederick L. Brancati, *Assessment of Medical School Institutional Review Board Policies Regarding Compensation of Subjects for Research-Related Injury*, 118 AM. J. MED. 175 (2005) (surveying 113 medical schools and finding that roughly one-fifth offered coverage for medical bills associated with research-related injuries, and of those, only half covered fees for emergency care).

<sup>22</sup> See eg Human Subjects Division, *Human Subjects Assistance Program*, UNIVERSITY OF WASHINGTON, March 27, 2015, <http://www.washington.edu/research/hsd/docs/1800> (last accessed July 28, 2015); Human Subjects Division, *HSAP Information Sheet*, UNIVERSITY OF WASHINGTON, updated Feb. 17, 2015, <http://www.washington.edu/research/hsd/docs/1801> (last accessed July 28, 2015). A previous iteration of this program applied to both healthy participants and participants in so-called therapeutic research. See Karen E. Moe, Director and Assistant Vice Provost for Research, University of Washington Human Subjects Division, presentation to Presidential Commission for the Study of Bioethical Issues, Nov. 17, 2011, <http://bioethics.gov/node/391> (last accessed July 28, 2015).

medical coverage for injured research participants.<sup>23</sup> The Department of Veterans Affairs, the Department of Defense, and the National Institutes of Health (NIH) Clinical Center, among others, also have policies that offer medical care to participants who suffer research-related injuries in agency-conducted clinical trials,<sup>24</sup> and Medicare covers the costs of care for some trial-related injuries.<sup>25</sup> Unfortunately, because these academic, government, and private programs cover only limited research populations, most participants in research remain unprotected when they sustain research-related injuries.

Trade representatives for pharmaceutical and biotechnology companies have asserted that many of them ‘carry insurance to cover the costs of research-related injuries’.<sup>26</sup> Because industry sponsors are not legally required to carry insurance, there are no guidelines for how much coverage they should have, which injuries are covered, what kinds of compensation they should offer, or even how and when research participants should be informed that compensation is available in case of injury. Importantly, there are no available data to demonstrate that sponsors reliably pay claims initiated by injured research participants. To the contrary, some critics suggest that industry insurance policies are so vaguely written that insurers typically avoid payment under their terms altogether.<sup>27</sup>

### The Litigation Lottery

Because most institutions and sponsors do not provide free medical care for research-related injuries, and almost none provide monetary compensation, injured

<sup>23</sup> See eg OFFICE OF THE HUMAN RESEARCH PROTECTION PROGRAM, UCLA, GUIDANCE AND PROCEDURE: TREATMENT AND COMPENSATION FOR RESEARCH RELATED INJURY, last updated Apr. 8, 2013, <http://ora.research.ucla.edu/OHRPP/Documents/Policy/10/Treatment.Compensation.pdf> (last accessed July 28, 2015) (not applying to research ‘designed to benefit the subject directly’).

<sup>24</sup> Since 1998, the Department of Veterans Affairs (VA) has provided medical treatment for injuries that participants suffer in research approved by a VA IRB and conducted under VA supervision. See 38 C.F.R. § 17.85(a) (2013). In 1999, the Department of Defense (DoD) enacted a similar policy, which mandates that all DoD research involving more than minimal risk include an arrangement to cover the treatment of any research-related injuries. See U.S. DEP’T OF DEFENSE, DOD INSTRUCTION NUMBER 6000.08: FUNDING AND ADMINISTRATION OF CLINICAL INVESTIGATION PROGRAMS 8 (updated Jan. 22, 2014). The NIH Clinical Center likewise provides free short-term medical care for injuries resulting from the participant’s participation in research at the Clinical Center. See OFFICE OF HUMAN SUBJECTS RESEARCH, NAT’L INSTITUTES OF HEALTH, SHEET 6: GUIDELINES FOR WRITING INFORMED CONSENT DOCUMENTS (Nov. 20, 2006).

<sup>25</sup> Centers for Medicare & Medicaid Services, *National Coverage Determination (NCD) for Routine Costs in Clinical Trials* § 310.1 (July 9, 2007) (‘Medicare covers the routine costs of qualifying clinical trials ... as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials.’). This approach is consistent with Medicare’s interest in encouraging clinical trial participation as a way to make medical care more data driven. Notably, the phrase ‘qualifying clinical trials’ does not include trials involving healthy volunteers. Larry D. Scott, *Research-Related Injury: Problem and Solutions*, 31 J. L. MED. & ETHICS 419, 421 (2003). As of January 2014, private insurers are also required to pay for routine care costs for participants in some types of clinical trials, but not all private insurers cover research-related injuries. 42 U.S.C. § 300gg-8 (2012). See also American Cancer Society, *Clinical Trials: What You Need to Know*, rev. Oct. 31, 2014, <http://www.cancer.org/treatment/treatmentsandsideeffects/clinicaltrials/whatyouneedtoknowaboutclinicaltrials/clinical-trials-what-you-need-to-know-private-insurers-a-c-a> (last accessed July 27, 2014). States may also have their own laws regulating insurance coverage for clinical trial participants. See American Society of Clinical Oncology, *Insurance Coverage for Clinical Trial Participants: State Laws and Cooperative Agreements*, <http://www.asco.org/insurance-coverage-clinical-trial-participants> (last accessed July 27, 2015).

<sup>26</sup> MORAL SCIENCE, *supra* note 6, at 66.

<sup>27</sup> See Carl Elliott, *Justice for Injured Research Subjects*, 367 NEW ENG. J. MED. 6, 7 (2012).

participants have few avenues for addressing their research-related health and financial injuries other than through the tort system. The tort system, however, presents several challenges for injured research participants, who can rarely meet the financial and evidentiary burdens of a successful legal claim. Although there are a few reported cases in which plaintiffs with research-related injuries prevail, these outcomes are generally limited to facts in which there was deficient informed consent, investigator conflict of interest, or fraud.<sup>28</sup> For the vast majority of injured research participants, the tort system is a costly, lengthy, and adversarial process that yields no remedy.<sup>29</sup>

Most research-related injury cases allege negligence, an action that requires plaintiffs to prove not only that the research team breached a duty to them, but also that the research intervention caused their injury, and that the research team was at fault. At each juncture in this process, the injured participant faces obstacles to recovery.<sup>30</sup> First, there is a growing consensus that as long as researchers comply with the federal regulations and satisfy IRB requirements prior to conducting research, they have satisfied their duty of care.<sup>31</sup> Second, proving causation is problematic for research participants, many of whom suffer from underlying medical conditions that make it difficult to determine whether their alleged injury is the result of the experimental intervention or their disease.<sup>32</sup> The last, and arguably most challenging, element of a tort claim for injured research participants is proving that the investigator, research institution, and/or sponsor are at fault.<sup>33</sup> Well-conducted research can and does sometimes result in injuries in the absence of negligence or wrongdoing, which is precisely why experimental trials are so important. But in the absence of fault, research participants are generally unable to successfully sue in tort.<sup>34</sup> Moreover, certain classes of injured research participants,

<sup>28</sup> See eg *Gelsinger v. Univ. of Pennsylvania*, No. 001885 (Pa. Ct. Com. Pl. filed Sept. 18, 2000) (alleging failure to adequately disclose risks during informed consent, financial conflict of interest, and fraud); *Diaz v. Hillsborough County Hospital Authority*, 165 F.R.D. 689 (M.D. Fla. 1996) (involving low-income women who claimed that, while pregnant and in labor, they were given a drug without being informed that it was experimental or that they could refuse to participate). The *Diaz* case settled before trial for \$3.8 million, and the *Gelsinger* case resulted in a multimillion dollar settlement. See Alice Dembner, *Lawsuits Target Medical Research*, BOSTON GLOBE, Aug. 12, 2002, at A1.

<sup>29</sup> Michelle M. Mello et al., *The Rise of Litigation in Human Subjects Research*, 139 ANNALS INTERNAL MED. 40, 42 (2003).

<sup>30</sup> See Pike, *supra* note 7, for a more detailed discussion of the substantive legal barriers injured research participants face in tort cases.

<sup>31</sup> *Id.* See also Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 247 (2003) (suggesting that most courts now use the federal regulations as the standard of care for informed consent in human subject research).

<sup>32</sup> Resnik, *supra* note 19, at 266; Scott, *supra* note 25, at 423.

<sup>33</sup> John A. Robertson, *Compensating Injured Research Subjects: II. The Law*, HASTINGS CENTER REPORT, Dec. 1976, at 29, 30.

<sup>34</sup> This outcome is further amplified in jurisdictions that limit or preclude recovery under the assumption of risk and contributory negligence doctrines. Because federal regulations require researchers to obtain informed consent, all participants sign a document indicating that they understand the risks posed by the clinical trial in which they enroll. In jurisdictions with assumption of risk doctrines, courts have limited recovery to injuries that are not mentioned in the informed consent document, reasoning that research participants assume the risks for all other injuries when they consent to participate. The doctrine of contributory negligence can further reduce the likelihood of recovery, particularly if there is evidence that the participant played a role in his or her injury. See E. Haavi Morreim, *Consumer-Defined Health Plans: Emerging Challenges from Tort and Contract*, 39 J. HEALTH L. 307, 311 (2006); Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 410–11 (2005).

including the US participants in federally conducted research and international participants in both privately and federally funded research, face additional legal barriers to recovery.<sup>35</sup>

### Gridlock

For 40 years, federal advisory panels have concluded that the absence of an adequate remedy for research-related injuries is inconsistent with the otherwise protectionist rules governing research with human participants.<sup>36</sup> These advisory panels have repeatedly recommended that the United States implement a no-fault compensation program and have noted that continued reliance on the tort system may be unjust. And yet, the primary mechanism for compensation remains the tort system. The absence of systematic no-fault compensation may result, in part, from a lack of political will, a mistaken belief that the current legal system offers sufficient recourse, and a desire to have more data about the nature of research injuries and the costs of addressing them.<sup>37</sup> The fact that research participants lack the solidarity, identity, and advocacy focus that enables other groups to function as collective bargaining units and demand better protections may also explain why change has not been forthcoming.<sup>38</sup> Finally, although numerous federal advisory committees have recommended no-fault compensation, their failure to coalesce around a moral justification for that duty has created ‘moral gridlock’ and impeded efforts toward systematic change.<sup>39</sup> Given the widespread national and international consensus that no-fault compensation is owed to injured research participants, the time is ripe for implementation of an ethically sound, administratively efficient, and financially feasible no-fault compensation plan.

### ETHICAL JUSTIFICATIONS FOR COMPENSATION

The no-fault system proposed in this article is grounded in the ethical principle of *compensatory justice*, which is the justification for no-fault compensation that has historically garnered the most support from federal advisory panels considering this issue.<sup>40</sup> Compensatory justice operates from the premise that there is an obligation to redress injuries suffered by individuals who undertake risks in an activity that is for the benefit

<sup>35</sup> See Pike, *supra* note 7, at 29, 38.

<sup>36</sup> MORAL SCIENCE, *supra* note 6, at 61, 62; Institute of Medicine, *Responsible Research*, *supra* note 3, at 191, 192; *Ethical and Policy Issues*, *supra* note 2, at 124; Presidential Advisory Committee on Human Radiation Experiments (ACHRE), *Final Report Recommendation 14* (1995) [hereinafter Final Report]; COMPENSATING FOR RESEARCH INJURIES, *supra* note 15, at 4; U.S. DEP’T OF HEALTH, EDUCATION, AND WELFARE, SECRETARY’S TASK FORCE ON THE COMPENSATION OF INJURED RESEARCH SUBJECTS: REPORT (1977) [hereinafter COMPENSATION OF INJURED RESEARCH SUBJECTS].

<sup>37</sup> See Henry, *supra* note 10, at 412, 421; Pike, *In Need of Remedy*, *supra* note 9, at 183. Some have argued that there are not enough research-related injuries to warrant implementing no-fault compensation. There are three responses. First, the data on compensation for research-related injuries are extremely limited, making it difficult to make far-reaching determinations on the scope of the problem. Second, as an ethical matter, even if the number of injured research participants is small, it is nevertheless unjust to require them to bear the physical and financial costs of their injury. And third, as a practical matter, if the number of injuries is small, the cost of implementing no-fault compensation should be quite low.

<sup>38</sup> See Elliott, *supra* note 27, at 7; Henry, *supra* note 10, at 421.

<sup>39</sup> Henry, *supra* note 10, at 412 (explaining that the various federal ‘committees’ articulation of numerous and sometimes disparate reasons for compensating injured research subjects actually results in incongruent obligations that favor different kinds of compensation systems’).

<sup>40</sup> *Id.* at 417.

of others.<sup>41</sup> The principle is one of fairness: when people are engaged in a collective enterprise, those who accept the benefits of that enterprise must compensate those who incur injuries on their behalf.<sup>42</sup> Veterans' benefits, for example, are provided to individuals who undertake risks to preserve national security. Ensuring that compensation is available for research-related injuries serves a similar end. It acknowledges and remedies the injuries that individual research participants may suffer in the broader quest to advance and improve the public's health.

Although federal advisory panels have generally agreed that compensatory justice ought to underpin a no-fault compensation system for research-related injuries, they have deliberated about other important questions, including whether all research participants—or only healthy volunteers in non-therapeutic research—qualify for compensation; whether the research enterprise or society is the beneficiary of research and thus the party obligated to compensate injured participants; and whether to offer acute medical care only, or also financial compensation for injuries.<sup>43</sup> These issues are addressed in turn.

First, the no-fault plan proposed in this article does not distinguish between types of research participants for eligibility purposes. Regardless of whether an injury is sustained in so-called therapeutic or non-therapeutic research, compensatory justice requires that compensation be available.<sup>44</sup> Although some federal committees have concluded that injured research participants in 'therapeutic research' have a 'weaker moral claim' for compensation than their counterparts in non-therapeutic research because the former participate 'with the hope of deriving personal health benefits',<sup>45</sup> that analysis is unpersuasive for two reasons. Not only do many patient participants expose themselves to greater risks in research than they would undertake in ordinary medical care, there is also no guarantee that their research participation will yield personal benefit. Moreover, compensatory justice does not focus on the individual's motivation in participating in a given activity; rather it emphasizes whether the activity is intended to benefit others. Just as a soldier's motivation for enlisting in the military has no effect on his or her qualification for veterans benefits, so too, the research participant's motivation for enrolling in a clinical trial should have no effect on his or her eligibility for compensation. In both cases, the relevant criterion is that an individual has undertaken risks by participating in an activity primarily intended for the benefit of others.

Second, the proposed no-fault plan places the compensatory obligation squarely on the research enterprise—research institutions and industry sponsors—rather than on society at large. Although the benefits of research ultimately redound to society,<sup>46</sup> the research enterprise is the better locus of primary responsibility for research-related

<sup>41</sup> James F. Childress, *Compensating Injured Research Subjects: I. The Moral Argument*, HASTINGS CENTER REPORT, Dec. 1976, at 21.

<sup>42</sup> This notion is sometimes characterized as distributive justice. See Resnik, *supra* note 19, at 266.

<sup>43</sup> Henry, *supra* note 10, at 417, 420.

<sup>44</sup> See Pike, *supra* note 7, at 55. See also Steven Joffe & Franklin G. Miller, *Bench to Bedside: Mapping the Moral Terrain of Clinical Research*, HASTINGS CENTER REPORT, Mar./Apr. 2008, at 30, 37–38 (suggesting that compensation is owed for injuries that occur in both therapeutic and non-therapeutic research).

<sup>45</sup> COMPENSATING FOR RESEARCH INJURIES, *supra* note 14, at 133. See also COMPENSATION OF INJURED RESEARCH SUBJECTS, *supra* note 36, at VI 8, 9 (discussing the 'serious reservations' some Task Force members had about compensating participants in therapeutic research).

<sup>46</sup> MORAL SCIENCE, *supra* note 6, at 56.

injuries for several reasons: it is the first party to ‘profit or derive other benefits’ from research,<sup>47</sup> its proximate relationship with research participants means it is best positioned to efficiently redress injuries, and it can internalize the costs of compensation or shift those costs to society downstream.<sup>48</sup> Moreover, by imposing responsibility on the research enterprise, the proposed plan reinforces the well-accepted ethical standards of professional beneficence and nonmaleficence.<sup>49</sup> Consistent with those duties, the system may appropriately reduce or eliminate some high-risk research, as institutions and sponsors weigh the costs of covering potential research-related injuries in higher risk trials against prospective benefits from those trials.

Third, because compensatory justice involves attempting to restore individuals to the state of affairs they enjoyed before their injury, the proposed no-fault system includes the provision of free, immediate medical care for research-related injuries as well as financial compensation for lost wages, disability, long-term medical care, and where indicated, death benefits.<sup>50</sup> In recommending monetary compensation in addition to acute medical care, the proposal acknowledges and responds to the ‘actual loss of wages and out-of-pocket costs directly resulting from research-induced injuries’.<sup>51</sup> In keeping with the requirements of compensatory justice, this approach aims to leave participants ‘no worse off than they would have been had they not participated in research’.<sup>52</sup>

Finally, it is important to note that the proposed no-fault compensation plan does not preclude participants who suffer research-related injuries from instead pressing their claim through the traditional tort system.<sup>53</sup> The tort system, which operates under the principle of reparative justice, is designed to ‘repair’ an injury to one party that is *wrongfully* caused by another. In cases where research-related injuries are the consequence of unethical research or wrongdoing by the research enterprise, the tort system’s focus on fault may offer a more morally appropriate and financially

<sup>47</sup> *Ethical and Policy Issues*, *supra* note 2, at 126.

<sup>48</sup> Guido Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499 (1961) (explaining that manufacturers can spread the risks of making a product across consumers through higher pricing, which represents the product’s true cost).

<sup>49</sup> MORAL SCIENCE, *supra* note 6, at 61 (noting that researchers ‘ought not to engage in such research unless they can be assured that there is a system in place to care for those harmed by research so that their duties of beneficence and nonmaleficence can be fulfilled’).

<sup>50</sup> Although compensatory justice aims to make people whole, no-fault compensation systems may fall short of this ideal as compared to the tort system with regard to some remedies (eg compensation for pain and suffering). Nevertheless, the vast majority of injured participants will fare better under the no-fault system than they do under the status quo. See *supra* section *Inadequacies of the Status Quo*. Moreover, receipt of immediate compensation without the need to sue in tort is itself a benefit that can justify some reduction in the total amount paid. Interview with Kenneth Feinberg, former Special Master of the Federal September 11th Victim Compensation Fund of 2001, and current Administrator of the General Motors Ignition Switch Compensation Program (July 2, 2014). See also Tatsuo Kuroyanagi, *Compensation and Insurance for Participants/Subjects Harmed in Clinical Research Studies: Process of the Inheritance of Good Clinical Practice (GCP) in Japan and Its Present Status*, 56 JAPAN MED. ASS’N J. 458, 461 (2013) (stating that compensation provided under Japan’s no-fault compensation system is set at seventy percent of what would be recoverable in tort because ‘in lieu of full payment the subject (worker) will receive payment of compensation quickly, even if the employer was not negligent’).

<sup>51</sup> COMPENSATING FOR RESEARCH INJURIES, *supra* note 14, at 143.

<sup>52</sup> *Ethical and Policy Issues*, *supra* note 2, at 123.

<sup>53</sup> Consistent with the federal rules, research participants under the proposed compensation system will not be asked during the informed consent process to waive any legal right or release any sponsor, institution, or researcher from liability for negligence. 45 C.F.R. § 46.116(a)(6) (2013); 21 C.F.R. § 50.25(a)(6) (2014).

remunerative approach to making an injured party whole again than the no-fault compensation plan offered here. The allowance of punitive damages in tort, for example, provides monetary compensation to the injured party, punishment for the bad act, and deterrence to future wrongful behavior. As this article noted at the outset, however, the vast majority of research-related injuries are not the result of wrongdoing, and are therefore the impetus behind—and the ideal candidates for—the no-fault compensation system proposed below.

#### WHAT FORM SHOULD A NO-FAULT COMPENSATION SYSTEM TAKE?

As the President's Commission noted in 1982, a just compensation system should treat like cases alike, make fair payment for the harm sought to be remedied, and disburse payments with maximum efficiency and minimum administrative cost.<sup>54</sup> It should incentivize research sponsors to manage and mitigate risks to participants—part of the package of research protections aimed at making the research enterprise safer. A just compensation system should be able to make nuanced determinations of causation. As a matter of administrative cost, it also should minimize new bureaucracy. Finally, a US no-fault compensation system should aim to meet or exceed the ethical standards for compensation set forth by international declarations and held by the United States' international research partners.<sup>55</sup>

Federal advisory panels have primarily focused on three types of no-fault compensation systems that could meet the criteria laid out above. One type of no-fault compensation scheme that has been proposed to address research-related injuries is a specialty court modeled on the Vaccine Court, which was established by the National Vaccine Injury Compensation Program (NVICP).<sup>56</sup> Congress intended the program to provide a 'swift, flexible, and less adversarial alternative' to tort lawsuits.<sup>57</sup> The NVICP permits individuals injured by vaccines to petition the federal government for compensation. Claimants present their medical records to the Vaccine Court to demonstrate that shortly after they were vaccinated, they developed one of several adverse events listed in the Vaccine Injury Table.<sup>58</sup> Compensation is provided by the Vaccine Injury Compensation Trust Fund, which is funded through a 75 cent surtax on the purchase of each vaccine.<sup>59</sup> Consequently, those who are vaccinated pay into the Fund that compensates those who are injured.

Since its inception, reviews of the Vaccine Court have been mixed, with some commentators contending that it works reasonably well, and others criticizing it for becoming too adversarial, having a severe backlog of cases, and only addressing a narrow range

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<sup>54</sup> COMPENSATING FOR RESEARCH INJURIES, *supra* note 14, at 127.

<sup>55</sup> See Pike, *supra* note 7, at 47, 48.

<sup>56</sup> National Childhood Vaccine Injury Act, Pub. L. No. 99-660 (1986).

<sup>57</sup> Vaccine Program/Office of Special Masters, U.S. COURT OF FED. CLAIMS, <http://www.uscfc.uscourts.gov/vaccine-programoffice-special-masters> (last accessed June 4, 2015).

<sup>58</sup> 42 C.F.R. § 100.3 (providing the Vaccine Injury Table). See also The Office of Special Masters, U.S. Court of Fed. Claims, Guidelines for Practice Under The National Vaccine Injury Compensation Program (2004), <http://www.uscfc.uscourts.gov/sites/default/files/OSM.Guidelines.pdf> (last accessed July 27, 2015) (setting forth the claim process).

<sup>59</sup> HEALTH RES. & SERVS. ADMIN., NAT'L VACCINE INJURY COMP. PROGRAM, <http://www.hrsa.gov/vaccinecompensation/index.html> (last accessed July 27, 2015) (describing the excise tax).

of all vaccine-related injuries.<sup>60</sup> Setting aside those criticisms, a specialty court is nevertheless inapt in the context of research-related injuries. Although a specialty court might aim to treat like cases alike and disburse payments with maximum efficiency and minimum administrative cost, it may not adequately incentivize safer research. For instance, because the Vaccine Court is funded by a surtax on all vaccines and immunizes vaccine manufacturers from liability, the existence of Court by itself provides vaccine manufacturers little incentive to mitigate risk. Moreover, unlike vaccine-related injuries—which arise from a defined set of vaccines and are generally predictable enough to be charted in a compensation table—the injuries arising from research emanate from thousands of clinical trials, are wide ranging, frequently unforeseeable, and involve more challenging and nuanced determinations of causation.<sup>61</sup> Additionally, the Vaccine Court was established to address the urgent national concern that tort lawsuits would force vaccine manufacturers out of the market altogether.<sup>62</sup> The significant political will required to create a new, stand-alone bureaucracy is unlikely to materialize in the context of compensating injured research participants.<sup>63</sup>

A second model that has been suggested to address research-related injuries is a no-fault compensation fund similar to the September 11th Victim Compensation Fund or the BP Deepwater Horizon Disaster Victim Compensation Fund.<sup>64</sup> With funds like these, an amount of money is appropriated, either by the federal government or a private party, to be disbursed to a defined group of people injured by a particular adverse event. Compensation funds of this kind satisfy some of the relevant criteria: the system tends to treat injured individuals alike and distribute compensation with maximum efficiency and minimum administrative burden.<sup>65</sup> Nevertheless, because these systems are retrospective—created after an injury-causing event occurs—they do not incentivize the relevant actors to mitigate risk of harm to others.

In addition, a national compensation fund would be both ill equipped to address the more complicated issues of causation that arise in the context of research-related injuries and would likely lack sufficient political will for implementation. For example, in order to facilitate expedient claims processing, the administrators of the September 11th and BP Deepwater Horizon Funds were able to articulate categories of claimants and compensable injuries based on knowledge of the triggering event rather than engaging in a detailed case-by-case causal analysis. Defining categories of eligible claimants would be challenging in the research context because a wide array of protocols and procedures can result in injury. Moreover, like the Vaccine Court, a national compensation fund for research-related injuries would likely require creation of a new

<sup>60</sup> Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD DRUG L.J. 351 (2001); Laura Mazzuca, *Shot Through with Problems: A Partial Success, Vaccine Injury Fund Faces Case Logjam, Funding Shortfalls*, BUS. INS., Aug. 24, 1992.

<sup>61</sup> See *infra* section *Claims Evaluation—Compensable Injuries, Causation*.

<sup>62</sup> See Scott, *supra* note 25, at 422.

<sup>63</sup> See *supra* section *Inadequacies of the Status Quo—Gridlock*.

<sup>64</sup> Department of Justice, *Final Report of the Special Master for the September 11 Victim Compensation Fund of 2001*, Vol. 1 (Nov. 17, 2004); Gulf Coast Claims Facility, <http://www.gulfcoastclaimsfacility.com/> (last accessed July 27, 2015) (succeeded by the Deepwater Horizon Claim Center, <http://www.deepwaterhorizoneconomicsettlement.com/>) (last accessed July 27, 2015).

<sup>65</sup> See Pike, *supra* note 7, at 52.

bureaucracy, a substantial obstacle in the absence of a particular triggering event that would shore up political will for injured research participants.

A final approach, and the one this article adopts, is that of a no-fault insurance/self-insurance plan. This type of plan—discussed in more detail in the next section—offers several advantages. Like a specialty court or national compensation fund, an insurance/self-insurance system can treat like cases alike and distribute compensation with maximum efficiency and minimum administrative burden.<sup>66</sup> Unlike a specialty court or compensation fund, however, this approach itself incentivizes research sponsors to manage and mitigate risks by forcing institutions to internalize the financial costs of research-related harms. In addition, an insurance/self-insurance plan best enables decision makers to make nuanced case-by-case determinations of causation.<sup>67</sup> Moreover, because individual institutions can implement this system voluntarily, the approach does not require the creation of a new centralized bureaucracy, and can therefore proceed in the absence of national political will. Finally, unlike a specialty court or national compensation fund, a no-fault insurance/self-insurance requirement best aligns with the approach taken by most foreign countries,<sup>68</sup> thereby allowing the United States to meet or exceed international legal norms related to compensation for research-related injuries.<sup>69</sup>

Some question whether modification of the United States' current approach to the problem of compensation for research-related injuries is needed at all. The fact is that the system *is* fundamentally broken. The United States continues to rely on a tort system that limits the success of almost all research-related injury lawsuits and on research participants' personal insurance as the primary means of compensation for research-related injuries. This approach falls far short of the goals of compensatory justice. The primary critique of implementing a no-fault compensation system is that it would be too costly to implement, an argument not borne out by empirical data.<sup>70</sup> More importantly, the costs of research-related injuries are not costs created by developing a

<sup>66</sup> Whether no-fault insurance/self-insurance plans are equitable across institutions, meaning they treat similarly injured research participants similarly, depends on how the system is implemented. If the system is set forth with specificity in federal regulations, see *infra* section *Modifying the Federal Framework*, it will treat like cases alike. If, instead, individual institutions separately and voluntarily adopt this approach, then there may be disparities in levels of compensation awarded to injured research participants across institutions. The definitions of eligible claimants, compensable injuries, and causation, see *infra* section *Creating a Fair and Efficient No-Fault System for Research—Related Injuries and Claims Evaluation*, aim to minimize these discrepancies in the absence of a federal framework.

<sup>67</sup> See *infra* section *Creating a Fair and Efficient No-Fault System for Research—Related Injuries and Claims Evaluation*.

<sup>68</sup> See Pike, *supra* note 7, at 49.

<sup>69</sup> MORAL SCIENCE, *supra* note 6, at App. IV (listing international and transnational requirements for compensating injured research participants).

<sup>70</sup> Data from the European Union's recent foray into insurance/self-insurance for research-related injuries suggest that the frequency of research-related injuries is low, the financial cost of providing compensation for these injuries is low, and the costs of insurance per patient per annum are also quite low. See EUROPEAN COMOTM'N OF HEALTH & CONSUMERS DIRECTORATE-GENERAL, REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC: CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION 8 (2011), [http://ec.europa.eu/health/files/clinicaltrials/concept\\_paper\\_02-2011.pdf](http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf) (last accessed July 28, 2015). See also Pike, *supra* note 7, at 60, 61 (describing the costs of providing compensating for research-related injuries in the European Union).

no-fault compensation system—they are costs that are currently absorbed by others (including injured research participants).<sup>71</sup>

### CREATING A FAIR AND EFFICIENT NO-FAULT SYSTEM FOR RESEARCH-RELATED INJURIES

The broad no-fault compensation system proposed in this article builds upon the success of smaller institution-driven programs that have a history of fairly and efficiently compensating injured research participants in the United States.<sup>72</sup> The recommended system also shares similarities with international no-fault compensation plans used to compensate injured research participants around the world,<sup>73</sup> and with no-fault compensation plans adopted in the United States in other contexts.<sup>74</sup> To successfully implement the proposed system, research institutions and sponsors must undertake four obligations: first, they must secure adequate funds—either by self-insuring or acquiring sufficient insurance—to provide medical care and financial compensation for research-related injuries; second, they must appoint an administrator to evaluate and manage claims; third, they must ensure that sufficient information about the compensation system is disclosed in the informed consent process; and fourth, they must maintain adequate records about the compensation system.

At the outset, however, it is essential to establish clear lines of responsibility for establishing, funding, and maintaining the compensation system. When research institutions engage in research without sponsors, the institution is responsible for administering the claims system and providing medical care and compensation, as described below. When research institutions conduct research with industry sponsors, the two parties should negotiate and allocate responsibility for administration of the claims system and for the costs of research-related injuries.<sup>75</sup> For trials that are industry sponsored but not conducted at research institutions (eg conducted by contract research

<sup>71</sup> The federal regulations already require certain research protections—most notably IRB approval of research and informed consent processes—that can be costly to administer. See 45 C.F.R. § 46.109, 21 C.F.R. § 56.103 (IRB review of research); 45 C.F.R. § 46.116, 21 C.F.R. § 50.20 et seq. (general requirements of informed consent). Although these costs could otherwise be spent on research, they are nevertheless deemed an essential part of an ethical research enterprise. Compensation for research-related injuries should be similarly understood as a necessary cost in conducting ethical research.

<sup>72</sup> MORAL SCIENCE, *supra* note 6, at App. III.

<sup>73</sup> ASS'N OF THE BRITISH PHARMACEUTICAL INDUSTRY, CLINICAL TRIAL COMPENSATION GUIDELINES (2014), [http://www.abpi.org.uk/our-work/library/guidelines/Documents/compensation\\_guidelines\\_2014.pdf](http://www.abpi.org.uk/our-work/library/guidelines/Documents/compensation_guidelines_2014.pdf) (last accessed July 27, 2015).

<sup>74</sup> See eg, GM IGNITION COMPENSATION CLAIMS RESOLUTION FACILITY, FINAL PROTOCOL FOR COMPENSATION OF CERTAIN DEATH AND PHYSICAL INJURY CLAIMS PERTAINING TO THE GM IGNITION SWITCH RECALL, June 30, 2014, <http://www.gmignitioncompensation.com/docs/FINAL%20PROTOCOL%20June%2030%202014.pdf> [hereinafter GM IGNITION SWITCH, FINAL PROTOCOL] (last accessed July 27, 2015).

<sup>75</sup> Industry sponsors and research institutions typically negotiate costs and responsibilities in their research contracts. See LEWIN GROUP, *supra* note 21, at 12. When institutions conduct research with government sponsors, institutions should propose a mechanism for compensating injured research participants that complies with the government regulations of the Anti-Deficiency Act and the Adequacy of Appropriations Act, including incorporating a request for funds into the grant proposal. *What Else Should I Know About Clinical Research?*, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT, Feb. 9, 2011, <https://www.nichd.nih.gov/health/clinicalresearch/clinical-trials/Pages/other-info.aspx> (last accessed July 27, 2015) (noting that ‘some clinical research sites carry insurance ... [which] can be a condition for allowing a site to participate in a particular federal study’).

organizations), the industry sponsor bears responsibility for administering the claims system and providing care and compensation to research participants. For multisite research, the expectation is that each institution has a system for compensating injured research participants enrolled in research at their site. Certain aspects of the compensation system could, however, be negotiated and allocated among the various sites.

## Institutional and Sponsor Responsibilities

### *Secure Adequate Funds*

Any institution or sponsor conducting human subjects research must secure adequate funds to cover potential claims.<sup>76</sup> Institutions and sponsors can indemnify participants by either self-insuring—setting aside funds to cover the costs of medical care and financial compensation for research-related injuries—or by purchasing private insurance that provides the same coverage. Historically, institutions have found it more cost effective to self-insure, as the cost of private insurance is often significantly higher than any injury payouts.<sup>77</sup> Institutions and sponsors are expected to set aside funds (or purchase insurance policies) sufficient to compensate injured participants, taking into account the number of trials currently being conducted or sponsored, the number of research participants currently enrolled in trials, and the riskiness of the research protocols.<sup>78</sup>

### *Appoint an Administrator*

Research institutions and industry sponsors must appoint an administrator to evaluate and manage claims. Research institutions and industry sponsors may either appoint an internal administrator or hire an independent third party to serve as administrator.<sup>79</sup> In either case, the administrator must be an individual or group that can receive initial injury reports, summon the resources and expertise necessary to evaluate the reports (including by bringing in specialists to help assess whether an injury is research related),

<sup>76</sup> This requirement applies to all institutions conducting human subjects research, including non-profit organizations, some of which already self-insure or purchase commercial insurance to compensate for research-related injuries. PHASES Legal Consultation, Johns Hopkins Berman Institute of Bioethics (Nov. 21, 2014) (notes on file with Leslie Meltzer Henry).

<sup>77</sup> See Moe, *supra* note 22 (explaining UW's shift from purchasing private insurance to self-insuring); HEALTH & CONSUMERS DIRECTORATE-GENERAL, EUROPEAN COMMISSION, REVISION OF THE 'CLINICAL TRIALS DIRECTIVE' 2001/20/EC, CONCEPT PAPER SUBMITTED FOR PUBLIC CONSULTATION 23, Feb. 9, 2011, [http://ec.europa.eu/health/files/clinicaltrials/concept\\_paper\\_02-2011.pdf](http://ec.europa.eu/health/files/clinicaltrials/concept_paper_02-2011.pdf) (last accessed July 27, 2015) (noting that in an unidentified European Union member state, the total amount of compensation paid out in fourteen claims over nine years was €43,000, while the cost of the insurance policy was approximately €235,000).

<sup>78</sup> Smaller institutions that are partnering with larger research centers or receiving grant money should take compensation for research-related injuries into account in making those financial arrangements. Ultimately, the amount that must be set aside is proportionate to the research risks taken on by the institution, and is subject to negotiation for contributions between the institution and research sponsors.

<sup>79</sup> An external administrator that administers a compensation system for a number of institutions offers the advantage of developing expertise in evaluating research-related injury claims, thereby streamlining the evaluation process and facilitating consistency in compensation across institutions. Choosing an external administrator may also eliminate real or perceived conflicts of interest. There are, however, some practical constraints that may make appointing an external administrator infeasible in this context. For example, if the number of research-related injuries is as low as some suggest, then the costs of hiring an outside administrator could significantly outpace compensation payments to injured research participants. Additionally, for many organizations, appointing an external administrator could cost more than naming an existing, internal employee to that position.

and disburse funds consistent with the parameters set forth below. The administrator should act in accordance with the mission of helping institutions and sponsors fulfill their ethical obligation to care for and compensate injured research participants.<sup>80</sup>

#### *Disclose the Availability of Compensation*

Information about the compensation system must be adequately disclosed during the informed consent process. Informed consent documents must (1) explain how participants can report a suspected research-related injury, including the contact information for the administrator in the event of a suspected research-related injury; (2) describe the claim evaluation process; and (3) include a statement that medical care and some types of financial compensation will be made available if a participant's injury is found to result from the research, but that punitive damages are not awarded under this compensation system. The informed consent document must also inform participants that they are expected to report a suspected injury to the administrator as soon as possible, but in all cases within one year of the incident that gave rise to the injury, and that evaluation of claims brought later than one year after the incident will be undertaken at the discretion of the administrator.<sup>81</sup> IRBs play an important role in ensuring that informed consent documents adequately provide all of this information to research participants.

#### *Maintain Adequate Records*

Even in the absence of a full-fledged no-fault compensation program, research institutions and sponsors can and should take immediate steps to maintain records about the number and types of research injuries reported, how those injuries are addressed, and the costs of addressing them. Once institutions and sponsors adopt no-fault compensation plans, they must also keep adequate records about the claims evaluation process for each claim brought under their program.<sup>82</sup> The expectation is that this information will help promote consistency in outcomes within and across institutions, and will provide additional data about the rates, types, and costs of research-related injuries.<sup>83</sup>

<sup>80</sup> The administrator is expected to negotiate fairly with injured research participants. One incentive to negotiate fairly is that a reasonable offer made by an institution and accepted by an injured research participant means that the claim will not subsequently be brought as a tort lawsuit. See *infra* section *Claims Evaluation—Waivers and Appeals*. Moreover, it is possible that as time passes, external third party evaluators will emerge in much the same way as have external IRBs. Institutions could therefore choose to outsource review of injury claims as a way of heightening assurances of impartiality.

<sup>81</sup> Injured research participants who fall outside the no-fault compensation system can still look to the tort system, although recovery in tort will remain a challenge for most research participants. See *supra* section *Inadequacies of the Status Quo*.

<sup>82</sup> This records retention process should comply with all relevant state and federal regulations concerning patient and research participant privacy.

<sup>83</sup> Lack of data is often cited as one reason that a no-fault compensation has not been implemented. See eg *Ethical and Policy Issues*, *supra* note 2, at 125 ('More information is needed about the nature and extent of research-related injuries and uncompensated research injuries.');

COMPENSATING FOR RESEARCH INJURIES, *supra* note 14, at 43 ('To determine the need for, and practical feasibility of, a compensation program, the Commission recommends that a small experiment be undertaken over a three to five-year period.'). The Presidential Commission for the Study of Bioethical Issues most recently recognized the lack of empirical data on this issue. See MORAL SCIENCE, *supra* note 6, at 64 ('The nature and extent of injury, the type of research in which the injury is occurring, and the costs of injury to subjects, investigators, and society have not been systematically studied.').

## Claims Evaluation

### Eligibility

Research participants in both therapeutic and non-therapeutic research are eligible to apply for no-fault compensation.<sup>84</sup> In the event of injury, a research participant or the participant's legal representative are the only eligible claimants.<sup>85</sup> In the event of disability or death, however, a participant's dependents may also be entitled to compensation. In such cases, the compensation system should generally rely on state law to determine eligible beneficiaries.<sup>86</sup> Accordingly, if a decedent has a will, that testamentary document determines the eligible claimant(s).<sup>87</sup> If the decedent does not have a will, state laws governing intestacy determine the eligible claimant.

### Compensable Injuries

To qualify as compensable,<sup>88</sup> an injury must first, be caused by research participation and, second, be the type of injury for which compensation is justified as an appropriate remedy.<sup>89</sup> As described below, an injury is compensable if the medical or financial harm was caused by research participation, and acute medical treatment was insufficient to mitigate the harm suffered.<sup>90</sup>

### Causation

The question of which injuries are *caused* by research participation is complex and has its roots in the traditional legal and scientific notions of causation.<sup>91</sup> To be eligible for compensation under the proposed system, a preponderance of the evidence must demonstrate that research participation was more likely than not a factual, or 'but for', cause of the participant's injury (ie the injury would not have occurred 'but for' the research participation).<sup>92</sup> Research injuries include those resulting from the administration of

<sup>84</sup> See *infra* section *Ethical Justifications for Compensation* and text surrounding footnotes 44 and 45.

<sup>85</sup> This approach has been used in numerous compensation systems and serves to limit the class of potential claimants to an appropriate and objectively verifiable universe. See eg GM IGNITION SWITCH, FINAL PROTOCOL, *supra* note 74. It is also consistent with hospitals' obligations to identify appropriate surrogate decision makers for incapacitated patients. See eg OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS, NATIONAL INSTITUTES OF HEALTH, STANDARD OPERATING PROCEDURE ON RESEARCH INVOLVING ADULTS WHO ARE OR MAY BE UNABLE TO CONSENT, June 26, 2013, [http://ohsr.od.nih.gov/ohsr/public/SOP\\_14E\\_v1.6-26-13.pdf](http://ohsr.od.nih.gov/ohsr/public/SOP_14E_v1.6-26-13.pdf) (last accessed July 28, 2015). See also 45 C.F.R. § 164.502(g) (2013) (allowing a patient's legally authorized representative to access patient files).

<sup>86</sup> See eg GM IGNITION SWITCH, FINAL PROTOCOL, *supra* note 74.

<sup>87</sup> See eg KENNETH R. FEINBERG, WHO GETS WHAT: FAIR COMPENSATION AFTER TRAGEDY AND FINANCIAL UPHEAVAL 72 (2012) (describing the approach taken in the 9/11 victims' compensation fund). This approach has the benefit of allowing hospital procedures to fit neatly into the legal systems of the states in which they are governed.

<sup>88</sup> A compensable injury is one for which financial compensation is owed.

<sup>89</sup> Pike, *supra* note 7, at 56.

<sup>90</sup> Acute medical care should be provided free of charge under the proposed no-fault system. If the research site does not have the capacity to provide acute care for injuries (eg a contract research organization facility), then any costs for acute care provided elsewhere are subject to reimbursement and should be considered a compensable injury.

<sup>91</sup> See Megan E. Larkin, *Defining Compensable Injury in Biomedical Research*, 25 HEALTH MATRIX 309, 354–55 (Spring 2015).

<sup>92</sup> The Restatement Third of Torts refers to this form of causation as 'factual causation', as well as by the more familiar 'but for test'. RESTATEMENT THIRD OF TORTS § 26 cmt. b (2010) ('A factual cause can also be described as a necessary condition for the outcome.'). See also David. W. Robertson, *The Common Sense of Cause in Fact*, 75 TEX. L. REV. 1765, 1768 (1997) (noting that the 'but-for test' is the most widely used test for factual causation); Larkin, *supra* note 91, at 363.

research interventions and those that arise from the performance of related medical procedures that would not be performed in the ordinary course of clinical care.<sup>93</sup> In these cases, it can be fairly said that research participation leads to a set of circumstances that differs materially from what would otherwise have occurred, and that set of circumstances leads to the injury.<sup>94</sup>

Questions of causation are more difficult to parse in cases where individuals are involved in so-called therapeutic research.<sup>95</sup> When determining whether a research-related injury has occurred in trials involving patient participants, one factor to consider is whether research participants were deprived of the standard of care treatment for their medical condition.<sup>96</sup> To determine whether a research-related injury has occurred, the decision maker should weigh the difference between what would have happened had the standard of care been administered and what actually happened as a result of the research procedures.<sup>97</sup>

Injuries that occur during research, but that are not attributable to the research itself (for example, a car accident that occurs *en route* to the research site) should not be eligible for compensation.<sup>98</sup> This limitation is both a matter of policy—limiting coverage to injuries that are within the scope of risk that the compensation plan is designed to address—and a matter of compensatory justice—ensuring coverage for injuries suffered in the course of undertaking risks for the benefit of others.<sup>99</sup> In cases where there is culpable or tortious conduct on the part of a third party, the tort system—rather than a no-fault compensation system—is better equipped to make an injured research participant whole.

<sup>93</sup> See Larkin, *supra* note 91, at 364, 368 (discussing the relationship between causation by omission and the standard of care). Determinations and attributions of causation are routinely made in the adverse-event reporting and medical malpractice contexts, and similar forces are at work here.

<sup>94</sup> *Id.* at 363.

<sup>95</sup> Compensatory justice nevertheless acknowledges that the decision to participate in research, which involves assuming additional research risks to produce societal benefit, warrants compensation when injuries result from research-related interventions. See *Id.* at 353; see also *supra* section *Ethical Justifications for Compensation* (providing an ethical justification for including patient participants, who are enrolled in so-called therapeutic research, in the class of potential claimants).

<sup>96</sup> Larkin, *supra* note 91, at 366, 367.

<sup>97</sup> See *Id.*

<sup>98</sup> To give another example, if an individual participates in research for a novel therapy intended to treat the participant's underlying condition, any injury incurred that is over and above what the participant would have suffered as a result of the natural progression of the underlying condition, would be entitled to compensation because participation in research, rather than the underlying disease, caused the participant's injury. However, when a patient participant's injury is caused or worsened by the patient's own failure to follow the trial protocol, attribution of cause to clinical trial participation may not be warranted. See *Id.* at 363, 364.

<sup>99</sup> See *supra* section *Ethical Justifications for Compensation* (discussing compensatory justice). Compensation is intended to redress injuries suffered by individuals who undertake risks in an activity that is for the benefit of others. This limitation on the compensation system is consistent with the approach taken in RESTATEMENT (THIRD) OF TORTS: PHYSICAL & EMOTIONAL HARM ch. 6 Special Note (2010) (eliminating the term 'proximate cause' in favor of the more precise term 'scope of liability'). Because there is no tortious conduct to define the scope of liability in a no-fault compensation plan, it is more appropriate to define the scope of liability by examining the types of risks that the compensation plan was put in place to guard against. See *Id.*; Larkin, *supra* note 91, at 361, 362. Some have claimed that only foreseeable risks should be compensable, but this position is untenable because research inherently involves risks that are unknown and unknowable, particularly for the research subject, who is in a position of information asymmetry. Limitations should therefore not be placed on the range of compensable injuries based on the foreseeability of the biomedical research risk. See *Id.* at 338 (citing MORAL SCIENCE, *supra* note 6, at 70).

### Degree and Type of Injury

In the absence of fault, compensation should be provided only in cases of demonstrable medical and financial injury.<sup>100</sup> Many research-related injuries may be small or insignificant in nature, requiring little or no further medical care and resulting in no financial harm.<sup>101</sup> For these injuries, compensation is unnecessary to redress the harm caused. For more serious injuries, however, compensation is required. All injuries requiring medical care beyond acute care warrant compensation.<sup>102</sup> Financial injuries, such as lost wages and disability, that stem from medical injuries should also receive compensation.

### Evaluation Process

Claims for compensation must be addressed fairly and efficiently by a system that is transparent and accessible to research participants. The compensation system is triggered when the system administrator is contacted by either a participant, who suspects he or she has suffered a research-related injury, or a principal investigator (PI), who reports a research-related adverse event. Regardless of how the claim arises, the administrator must open a case file and request a preliminary determination from the PI about the likelihood that the participant's injury was caused by research participation. Because the PI often has the most detailed knowledge of the research protocol and any underlying medical conditions being studied, he or she is generally best qualified to determine whether a participant's symptoms reflect a possible adverse reaction to the study intervention or procedures, or are instead unrelated to the study or related to the natural progression of the participant's underlying illness.<sup>103</sup> PIs are expected to make fair and timely preliminary determinations (ie, within 7 days of the initial report, or sooner if circumstances demand).

After the administrator receives the PI's preliminary determination, the administrator must notify the participant of that determination and grant the participant notice of a right to be heard during the claims evaluation process. This includes the right to present documentary evidence of the nature and extent of any injury—both physical and financial—and the relatedness of the injury to research.<sup>104</sup> Once in possession of all relevant evidence, the administrator must evaluate the information and make a final determination about whether the participant's injury is compensable. If after reviewing

<sup>100</sup> See Larkin, *supra* note 91, at 370, 371 (arguing that no-fault compensation is only required in cases of medical and financial injury, and that intangible harms, such as dignitary or spiritual injuries may be addressed by other mechanisms).

<sup>101</sup> See Pike, *supra* note 7, at 57 ('Minor injuries, such as bleeding or bruising, should be dealt with on-site and on-the-spot.').

<sup>102</sup> For these purposes, health care includes medical care, mental health care, dental care, and physical therapy.

<sup>103</sup> PIs may not be entirely free from conflicts of interest. On the one hand, they may have an interest in maintaining an unblemished safety record, which could influence them to make a decision that injuries are unrelated to the research. Alternatively, PIs may be interested in protecting their research participants, which could lead them to favor compensation, regardless of whether the injury is actually research related. The review and appeals process are intended to safeguard the participants and institution/sponsor from these potential conflicts.

<sup>104</sup> GM IGNITION SWITCH, FINAL PROTOCOL, *supra* note 74, at 11 ('Both the individual claimant and GM reserve the right to submit to the Facility any information deemed relevant to the Administrator's evaluation and determination of any such Individual Death Claim or Category One Physical Injury Claim before the final processing and determination of the claim.').

all evidence, the administrator determines that it is more likely than not that the participant's injury *was* caused by the research, compensation should be offered commensurate with the injury suffered.<sup>105</sup> If, taking into account all evidence presented as viewed in the light most favorable to the research participant, the administrator determines that the injury is *not* research related, no compensation will be offered.<sup>106</sup> Administrators are expected to make determinations in a fair and timely manner (ie within 60 days, or faster if circumstances demand).

### *Remedies*

Separate and apart from compensation, medical care must be made available in proportion to the seriousness of the underlying research-related injury. Acute medical care for research-related injuries must be provided and should, when possible, be provided free of charge. If the participant is billed for the cost of acute care necessary to mitigate the harm from a research-related injury, he or she should be reimbursed through the no-fault compensation system.<sup>107</sup> With respect to long-term medical care, the compensation plan should offer injured research participants a choice of receiving either long-term medical care at the institution where they suffered the injury, or a lump sum payment designed to compensate for the cost of future medical needs. In addition to compensation for medical care, financial remedies available should include payment for disability (either short or long term) and a death benefit available to the next of kin.

Disability payments for both long-term and short-term disabilities should be tied to a recognized national standard.<sup>108</sup> Short-term disability payments are warranted only if the financial burden from missed work and attendant costs is greater than what would ordinarily be required of trial participants.<sup>109</sup> Long-term disability, by contrast, is compensable whenever the participant is likely to suffer lasting health effects of the

<sup>105</sup> See *supra* section *Causation*. To award compensation, the administrator must determine that 'it is more likely than not that ... the [claimant's] harm would not have occurred' if the claimant had not participated in the research trial. RESTATEMENT THIRD OF TORTS: PHYSICAL & EMOTIONAL HARM, § 26, cmt. *l*.

<sup>106</sup> Administrators are encouraged to evaluate claims favorably on behalf of injured research participants because injured research participants are at an informational disadvantage in trying to prove that their injury was research related.

<sup>107</sup> It should be recognized that this provision may raise questions related to coordination of benefits when the participant has private or government-provided insurance. See *infra* notes at 115–121 and surrounding text.

<sup>108</sup> See eg Federal Employees Compensation Act, 5 U.S.C. §§ 8105–8106 (2012), setting disability benefits at 66 2/3 per cent of an employee's monthly pay or '66 2/3 percent of the difference between his monthly pay and his monthly wage-earning capacity after the beginning of the partial disability'. This is also the approach suggested by the U.S. DEP'T OF HEALTH, EDUCATION, AND WELFARE, SECRETARY'S TASK FORCE ON THE COMPENSATION OF INJURED RESEARCH SUBJECTS: REPORT II-2 (1977). But see Division of Coal Mine Worker's Compensation, *Black Lung Monthly Benefit Rates for 2015*, U.S. DEP'T OF LABOR, <http://www.dol.gov/owcp/dcmwc/regis/compliance/blbene.htm> (last accessed Feb. 5, 2015). (which sets the benefit for all coal miners based on the equivalent disability payment for an employee at GS-2, Step 1).

<sup>109</sup> For example, if a participant is participating in a clinical trial wherein participants are expected to be hospitalized for 10 days and suffers a complication during the trial, which would ordinarily have required hospitalization if it had occurred out of the trial setting, but did not require any actual lengthening of the participant's hospital stay or time away from work, no compensation beyond the cost of treatment would be owed.

research-related injury, and those effects either prevent or limit the participant's ability to work.<sup>110</sup>

Both death and disability benefits should be paid in an amount that does not vary based on an individual participant's income, and that keeps pace with inflation.<sup>111</sup> A standard amount avoids exacerbating existing income inequalities,<sup>112</sup> prevents the creation of incentives for institutions to select research participants solely from low-income populations, promotes expedient distribution of funds, and leads to consistent protection for injured research participants across institutions.<sup>113</sup> Institutions may go beyond the standard required payment if so desired.<sup>114</sup>

Institutions that implement no-fault compensation should work with the relevant stakeholders (including private insurers, Medicare, and Medicaid) to coordinate benefits (eg payments for medical care, disability, and death);<sup>115</sup> to ensure that claims are paid correctly; and to avoid duplicate payments.<sup>116</sup> Billing departments at larger institutions already negotiate the coordination of benefits for clinical care. Coordinating benefits in the research context would therefore be only a minor expansion of existing negotiations. Smaller institutions may, however, find the process of coordinating benefits more challenging.

Institutional compensation policies must also be mindful of Medicare Secondary Payer provisions. Under these provisions, Medicare does not pay certain expenses or

<sup>110</sup> See eg 5 U.S.C. §§ 8105–8107 (2012). Whether or not research participants should also be compensated for their time spent as research participants is beyond the scope of this article, but subject to robust debate within the bioethics literature. See eg Holly F. Lynch, *Human Research Subjects as Human Research Workers*, 14 *YALE J. HEALTH POL'Y LAW ETHICS* (2014); Christine Grady, *Payment of Clinical Research Subjects*, 115 *J. CLIN. INVEST.* 1681, 1687 (2005).

<sup>111</sup> Benefits could be tied, for example, to a grade of the Federal General Schedule (GS) salary. The GS is adjusted to rise with inflation, and, if cost of living adjustments were omitted, would be uniform across the country. Such an approach has already been taken by at least one federal compensation program. See eg Division of Coal Mine Worker's Compensation, *supra* note 108 (which sets the benefit for all coal miners disabled by black lung disease at a percentage of the base salary of a Federal employee at level GS-2, Step 1). See also 30 U.S.C. § 901 *et seq.* (2012); 20 C.F.R. § 726.203(c)(4) (2014).

<sup>112</sup> See FEINBERG, *supra* note 87, at 68 (explaining that compensation systems that are deliberately de-coupled from the tort system, in favor of equality of payment, are a way of promoting healing).

<sup>113</sup> Genevieve M. Grant et al., *Relationship Between Stressfulness of Claiming for Injury Compensation and Long-Term Recovery: A Prospective Cohort Study*, 71 *JAMA* 446 (2014). The amounts paid out by institutions do not need to be 'joined at the hip' to tort damages in order to deter potential litigants. See FEINBERG, *supra* note 87, at 100,102.

<sup>114</sup> This article does not set forth a precise amount that should be paid. Such a determination, if made on a national scale, is more appropriately made using notice and comment rulemaking under the Administrative Procedure Act. See 5 U.S.C. § 553. Use of the administrative rulemaking process would give interested parties with the relevant expertise a full and fair opportunity to have input into the determination of the appropriate national compensation rate. This article also does not propose a mandatory limitation on liability: Developing a formula for determining the amount of compensation, combined with accurately assessing the riskiness of an institution's research portfolio, provides an adequate basis for predicting future claims. Institutions may wish to set their own caps on liability for other practical or actuarial reasons, but there is no compelling ethical basis for doing so.

<sup>115</sup> It should be noted that coordination of benefits does not necessarily mean that private insurance pays before the no-fault compensation program; it simply means that the relevant payers allocate payment responsibility. The apportionment of cost sharing among the parties is subject to relevant contracts, statutes, and regulations in addition to the particular facts of each case.

<sup>116</sup> See eg *Coordination of Benefits*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Coordination-of-Benefits/Coordination-of-Benefits.html> (last accessed July 28, 2015).

claims if another entity is responsible for paying.<sup>117</sup> Per these provisions, no-fault compensation systems are considered primary payers, and Medicare generally will not pay for an injury or illness covered by no-fault compensation.<sup>118</sup> Similar requirements apply under Medicaid Third Party Liability provisions, which require states to seek payment for medical expenses from liable third parties before paying a claim from Medicaid funds.<sup>119</sup> Accordingly, institutions and sponsors should be aware that offers to provide no-fault compensation may affect payment otherwise due to Medicare or Medicaid recipients.<sup>120</sup> This administrative barrier could be overcome if the Medicare Secondary Payer provisions and analogous Medicaid Third Party Liability requirements were modified so that payments made under a no-fault compensation system were exempted from consideration in the application of those provisions, or, alternatively, if the Centers for Medicare and Medicaid Services provided guidance on when and how the secondary payer and third party liability provisions should be applied to injured research participants who are also Medicare or Medicaid beneficiaries.<sup>121</sup>

### *Waivers and Appeals*

A research participant's acceptance of an offer of financial compensation made under this system extinguishes future legal claims against the institution or sponsor arising from the injury, and a statement to that effect should be signed by all parties.<sup>122</sup> Injured participants who reject the administrator's decision can either request alternative dispute resolution with a mutually acceptable, independent expert paid for by the institution or sponsor, or they may bring suit.<sup>123</sup>

<sup>117</sup> *Medicare Secondary Payer*, CENTERS FOR MEDICARE & MEDICAID SERVICES, <http://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Coordination-of-Benefits-and-Recovery-Overview/Medicare-Secondary-Payer/Medicare-Secondary-Payer.html> (last accessed July 28, 2015).

<sup>118</sup> *Id.*

<sup>119</sup> See 42 U.S.C. § 1396a, § 1902 (2012). See also CENTERS FOR MEDICARE & MEDICAID SERVICES, DEFICIT REDUCTION ACT IMPORTANT FACTS FOR STATE LAWMAKERS (Dec. 11, 2007), <http://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/tpl.pdf> (last accessed July 27, 2015). Compare with *Medicare Secondary Payer*, *supra* note 117. See also 42 U.S.C. § 1395y(b) (2012) [section 1862(b) of the Social Security Act]; 42 C.F.R. Part 411 (2013).

<sup>120</sup> In the event of uncertain no-fault payments, Medicare may make a conditional payment so that a beneficiary will not have to go out of pocket to pay medical bills. The payment must be repaid once a settlement or other payment is made. *Medicare Secondary Payer*, *supra* note 117.

<sup>121</sup> While most payers are considered to be primary payers to Medicare, *Id.*, or Medicaid (under Medicaid provisions this is referred to as 'third party liability'), there are some existing exemptions including services provided through Ryan White programs. See 42 U.S.C. § 300ff-25(b)(2) (2012).

<sup>122</sup> This requirement does not violate the federal prohibitions on exculpatory language, see 45 C.F.R. § 46.116 (2013) and 21 C.F.R. § 50.20 (2014), because the waiver is not given during the informed consent process, but instead only upon receipt of compensation for a research-related injury. See also GM IGNITION SWITCH, FINAL PROTOCOL, *supra* note 86, at 10 ('In order for the claim to be eligible for payment, all claimants must consent to participate in the Facility and agree to be bound by its terms, but shall not release any legal rights until an award is determined, the claimant is notified, and the claimant accepts the award and executes a binding release.');

ASS'N OF THE BRITISH PHARMACEUTICAL INDUSTRY, *supra* note 73, § 5 ('[P]atients will normally be asked to accept that any payment made under the Guidelines will be in full settlement of their claims.').

<sup>123</sup> ASS'N OF THE BRITISH PHARMACEUTICAL INDUSTRY, *supra* note 73, § 4.3 ['In any case where the company concedes that a payment should be made to a patient but there exists a difference of opinion between company and patient as to the appropriate level of compensation, it is recommended that the company agrees to seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his opinion should be given substantial weight by the company in reaching its decision on the appropriate payment to be made.'].]

## MODIFYING THE REGULATORY FRAMEWORK

Incorporating the proposed system into the existing legal framework requires modification of the two primary regulations that currently govern much of the biomedical research conducted in the United States: The Common Rule, which applies to research at institutions receiving federal funding, and the Food and Drug Administration (FDA) regulations, which applies (among other activities) to research that supports applications for drug and device approval.<sup>124</sup> These regulations currently require that participants be told whether compensation for research-related injuries will be made available, but do not require institutions or sponsors to provide such compensation.<sup>125</sup> An amendment requiring, instead, that research institutions and sponsors ensure appropriate care and compensation for research-related injuries would effectively cover most human subjects research conducted in the United States.<sup>126</sup> In the absence of regulatory action, research institutions and sponsors should begin implementing the no-fault compensation system proposed above, and funders—like the NIH and others—should make compensation a condition of receiving funds.<sup>127</sup> Doing so is an important step toward harmonizing institutional policies both nationally and internationally, and toward fulfilling an important ethical obligation.

## CONCLUSION

Biomedical research plays an undeniably important role in developing life-sustaining and life-enhancing medical advances, but this progress comes at a cost. Research, no matter how well designed and ethically conducted, carries uncertainties and exposes participants to risk of injury. When injury occurs, compensatory justice—coupled with the well-accepted ethical principles of professional beneficence and nonmaleficence—requires that research participants not be left worse off as a result of their participation.

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<sup>124</sup> The FDA regulations apply to ‘all clinical investigations regulated by the Food and Drug Administration under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act, as well as clinical investigations that support applications for research or marketing permits for products regulated by the Food and Drug Administration, including foods, including dietary supplements, that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.’ 21 C.F.R. § 50.1 (2014).

<sup>125</sup> 45 C.F.R. § 46.116(a)(6) (2013); 21 C.F.R. § 50.25(a)(6) (2014).

<sup>126</sup> The Common Rule currently applies, with some exceptions, to ‘all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research’. 45 C.F.R. § 46.101 (2013).

<sup>127</sup> In addition, the NIH can provide extramural funds for compensation, consistent with its grant-making authority. See eg *NIH Grants Policy Statement*, NIH OFFICE OF EXTRAMURAL RESEARCH (Oct. 2013), [http://grants.nih.gov/grants/policy/nihgps.2013/nihgps\\_ch7.htm#direct\\_indirect\\_costs](http://grants.nih.gov/grants/policy/nihgps.2013/nihgps_ch7.htm#direct_indirect_costs) (last accessed July 28, 2015); U.S. GOV’T ACCOUNTABILITY OFFICE, GAO-13#760, BIOMEDICAL RESEARCH: NIH SHOULD ASSESS THE IMPACT OF GROWTH IN INDIRECT COSTS ON ITS MISSION (September 2013), <http://www.gao.gov/assets/660/658087.pdf> (last accessed July 28, 2015). This mechanism, by which the NIH allocates funds to grant recipients for no-fault compensation, complies with the Adequacy of Appropriations and Anti-Deficiency Acts. 31 U.S.C. § 1341(a)(1)(A); 41 U.S.C. § 11(a). These acts, which generally limit the government’s ability to incur future financial obligations that have not yet been appropriated, would not preclude the NIH from appropriating extramural grant funds for compensation, so long as the compensation was limited to the amount allocated in the grant. See COMPENSATION OF INJURED RESEARCH SUBJECTS, *supra* note 14, at V-4 (‘[I]f institutions chose to fund such a system with insurance, the premiums ascribable to the insurance could be paid from grant or contract funds under current department policies.’). Implementing a no-fault insurance/self-insurance program for federal agencies presents additional, but not insurmountable challenges.

This ethical analysis is not novel. For more than four decades, national advisory bodies have considered research-related injuries and have repeatedly concluded that participants are entitled to receive medical care and financial compensation for research-related injuries. Despite consensus on this point, no steps have been taken to implement systematic no-fault compensation for research-related injuries in the United States. Rather, injured research participants are left to the vagaries of the tort law system, an approach that leaves participants to either shoulder the physical and financial burdens of their research-related injuries alone or play the 'litigation lottery', with its daunting odds.

Certain institutions have taken steps to provide no-fault compensation to injured research participants, but these institutions remain the exceptions to the rule. Without uniform and systematic no-fault compensation, the inconsistent policies of institutions and sponsors leave many research participants unprotected and provide uneven redress for others. This inconsistency, which is intensified by the growth of multisite research and the move to single-IRB review, is ethically unjustifiable and pragmatically untenable.

This article therefore proposes a no-fault compensation system that aims to treat like cases alike, offer just compensation for the harm sought to be remedied, and disburse compensation with maximum efficiency and minimum administrative cost. This approach should be mandated by modification of the regulations governing research, and in the meantime, voluntarily adopted by research institutions and industry sponsors. By describing the eligible claimants, defining compensable injuries, establishing the remedies to be provided, and setting forth a standardized process for evaluating claims, the system proposed in this article seeks to rectify an ethical infirmity that has endured for far too long.

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