

Compensation for Research-Related Injuries: Ethical and Legal Issues

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INTRODUCTION

The rapid increase in litigation related to biomedical research on human subjects has highlighted the importance of developing policies addressing compensation for research-related injuries.¹ Although the United States federal research regulations do not require researchers, sponsors, or research institutions to offer subjects compensation for injuries, they do require researchers to discuss compensation for injury with subjects during the informed consent process, if the research is classified as more than minimal risk.

According to the Common Rule, a regulation adopted by 17 federal agencies, one of the required elements of informed consent is, “For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or whether further information may be obtained.”² Although all institutional review boards (IRBs) must deal with this issue when they review research classified as more than minimal risk, there has been not been a large amount of legal or ethical scholarship on the topic of compensation for research injuries.³ This article explores some of the legal and ethical issues in compensating subjects for research-related injuries and describes some of the policies adopted by different institutions. The article argues that the current system of compensation for research-related injuries in the United States is unjust, and that that federal government should revise the human subjects research regulations to set a minimum standard for compensation.

I. RESEARCH-RELATED INJURIES

A research-related injury is an injury that occurs to a subject as a result of research participation. Injuries may range from relatively minor harms (such as bruises or infected wounds) to major injuries (such as organ damage or temporary disability) to catastrophic injuries (such as permanent disability or death). An injury may require only acute or emergency care, or it may require continuing care. Injuries can be physical or psychological/emotional. For example, suppose that a subject with a defective mitral valve has an experimental valve placed in the heart. Unfortunately, five days after placement, the valve malfunctions and the subject has a cardiac arrest. The subject loses consciousness, falls, and breaks the right wrist. Physicians perform an emergency procedure to remove the valve and put in a non-experimental one. After the surgery is completed, the physicians discover that the patient has sustained some damage to the heart, which will require lifetime treatment with a cardiac medication. The subject has also sustained severe brain damage. As a result of the damage to the brain, the subject is paralyzed from the neck down and no longer can speak. The subject is 45 years old, has a wife and two dependent children, and has been earning \$100,000 per year. In this hypothetical example, the subject suffers minor, major, and catastrophic injuries. He sustains physical and psychological harms. His injuries require acute, emergency, and continuing care. In a case like this, the subject's family might sue for many different kinds of damages, including the cost of medical care, other economic losses, pain and suffering, and death. These costs easily could run into millions of dollars, especially

when one considers the amount of money required to provide medical care to the patient for the rest of his life and the loss of his potential income.

There are no recent data on research-related injuries, but some older studies suggest that injuries, especially major or catastrophic injuries, are rare. A survey published in 1976 of 331 researchers conducting research on 133,000 subjects found in a three-year period, there were 4,957 injuries, 3,926 of which were classified as trivial. Nine hundred and seventy four injuries resulted in temporary disability, and 57 injuries resulted in death or a permanent disability. These data suggest an injury rate of about 12 injuries per 1,000 subjects per year, and a catastrophic injury rate of only about 14 per 100,000 subjects per year, if one assumes that only one injury is reported per person. If most subjects have more than one injury, then the injury rate per subject could be much lower. The study authors concluded the risks of participating in research that is also designed to provide medical benefits to the subject (sometimes called “therapeutic research”) are not greater than the risks of medical treatment.⁴

A survey of Phase I drug trials published in 1986 reported one death per 27,000 subjects and 13 serious reactions.⁵ If one assumes none of those adverse reactions resulted in permanent disability, this finding would translate into a catastrophic injury rate of about four per 100,000 subjects. A literature review revealed no recent studies on the injury rate in clinical research. Obviously, more data are needed concerning this issue.

II. THE ETHICAL BASIS FOR COMPENSATION

There are some compelling ethical (or moral) reasons for compensating subjects for injuries that occur as a result of participation in research. The Belmont Report, which provided a rationale for the current federal research regulations, is one of the most important documents in the United States for ethical guidance relating to research on human subjects. The report articulated three ethical principles for research: respect for persons, beneficence, and justice.⁶ The principle of beneficence requires researchers to minimize harms to their subjects (“do no harm”) and to maximize benefits. If a subject has been harmed in research by a research-related injury, beneficence obligates researchers to try to minimize the additional harms that may occur to the subject as a result of the injury. Researchers can fulfill this obligation by providing the subject with medical care or financial compensation. Ideally, subjects should be no worse off than they would be had they not participated in research.⁷

The principle of justice requires the benefits and burdens of research be distributed fairly. Researchers, research sponsors and research institutions often benefit from research. Subjects also may benefit from their participation. For example, in a clinical trial, a subject may benefit from receiving an effective therapy, financial compensation, or both. When all parties obtain significant benefits from research, there usually are not problems distributing benefits and burdens fairly. However, if one party, such as a research subject, bears a heavy burden, such as an injury, fairness demands that the subject receive some form of medical treatment or compensation.⁸ This is especially important when the subject does not have any health insurance to pay for medical care.

Even though one can make a strong moral case for compensating subjects for research related injuries, there may be administrative and financial problems in

implementing a compensation plan. First, as will be discussed later, it may be difficult to determine whether an injury was caused by a research study, the subject's underlying illness, the subject's failure to follow instructions, or some other cause.⁹ Although courts and workers' compensation panels answer questions like these on a daily basis, it still may be difficult to establish a reliable and efficient system for deciding when subjects have research-related injuries. For a compensation system to be fair, it must have a method for determining who deserves to be compensated and who should be required to pay for the compensation, because fairness requires that parties receive what they deserve and pay what they owe.¹⁰ Second, compensating subjects for injuries may constitute a financial hardship for researchers, sponsors, or institutions in some cases. There may be situations where researchers, sponsors, or institutions do not have enough resources to compensate subjects fully or establish an effective compensation program.¹¹

Although there may be some practical problems with establishing a fair or effective compensation program, one might argue that these difficulties do not undercut the moral duty to compensate subjects for injuries. It often is the case that people encounter practical difficulties in fulfilling their moral obligations. For example, suppose that a man borrows \$500 from his neighbor and promises to pay it back within six months. A week after he receives the money, he loses his job. Although losing his employment may make it more difficult for him to keep his promise to his neighbor, he still would have a moral obligation to keep that promise. Likewise, researchers, sponsors, and institutions have an obligation to compensate subjects for injuries, despite the practical difficulties they may encounter in meeting this obligation.

III. THE LEGAL BASIS FOR COMPENSATION

Research subjects have a right to seek redress for their injuries through the legal system. If a subject is injured during research, he or she may be able to bring a lawsuit against many different parties implicated in the injury, including: researchers; research staff, such as nurses or patient advocates; institutions, such as universities, medical centers, or hospitals; sponsors, such as pharmaceutical or medical device companies; and even institutional review board members. Most of the causes of action brought against defendants in research litigation have involved various torts, such as battery, negligence, fraud, misrepresentation, conversion, unjust enrichment, breach of fiduciary duty, violation of informed consent, products liability, intentional infliction of emotional distress, and wrongful death. Some lawsuits against government agencies or institutions have sought compensation for civil rights violations, and a small number of cases have addressed breaches of contractual duties.¹² Although there are no data on the success rate of human research lawsuits, it may be reasonable to extrapolate from data on medical malpractice cases, which are settled out of court 96% of the time.¹³ When plaintiffs manage to get a verdict at trial, they win less than 30% of the time.¹⁴ A malpractice claim is filed in only one out of eight cases of medical error that results in an injury.¹⁵ If these percentages also hold for human research lawsuits, then most subjects who have research-related injuries will not bring a lawsuit. When subjects do bring litigation, their cases will be settled out of court most of the time. And if a case ever goes all the way through a trial, the plaintiff will lose most of the time.

Even though the chances are probably very small that subjects will bring litigation for their injuries, the liability risks still are a cause for great concern. Lawsuits can be very stressful, cost millions of dollars in legal fees, and continue for many years until they finally are dropped, settled out of court, or adjudicated. It is quite reasonable, therefore, for researchers, institutions, and sponsors to take steps to avoid litigation or minimize its impact. A plan for providing subjects with compensation for research-related injuries can help lower the risks of litigation by encouraging subjects to seek help through the plan, instead of seeking legal redress. It makes good sense, from a legal risk management perspective, to purchase insurance or set aside funds to compensate subjects for research-related injuries and develop a system for administering the plan.

Although this legal risk management perspective provides a sound justification for adopting a compensation plan, it also creates some ethical and legal problems. The first problem arises in trying to limit legal liability associated with developing a plan. Suppose that a research sponsor wants to offer to pay for medical treatment for injuries caused by research participation, but nothing more. Someone who develops the language used to communicate the plan to subjects may be tempted to try to minimize legal risks by requiring potential plaintiffs (in other words, research subjects) to forego some legal rights to participate in research. For example, a research sponsor might develop an informed consent document with the following language: “Company X will provide you with compensation for medical treatment for injuries that are caused by your participation in this research study. Company X will not compensate you for pain or economic harms.”

The trouble with this statement that is might be interpreted as a waiver of specific legal rights, such as the right to sue the sponsor for pain or economic damages. If a subject signed a document containing the above statement, Company X would argue that the subject was, in effect, agreeing not to sue the company for the costs of pain or economic harms, because the subject accepted the statement in the document that Company X would not compensate for pain or economic harms.

From the sponsor's perspective, encouraging the subject to waive a right to sue for pain or economic harms is an effective way of managing legal risks and minimizing the costs of the compensation plan. However, this risk management strategy conflicts with the following Common Rule's requirement: "No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."¹⁶ The federal regulations require that informed consent documents not contain exculpatory language in which the subject gives up (or appears to give up) a right to sue the researcher, sponsor, or institution. Signing a statement that "Company X will not compensate you for pain or economic harms" appears to do just that. It is exculpatory language that should not be used in written or oral communications with the subjects.[17]

When IRBs review compensation for injury statements provided by sponsors, they are obligated to ensure that exculpatory language does not appear in the informed consent document. An IRB reviewing the statement from Company X should withhold approval of the research study until the statement is modified. A non-exculpatory way to

word this compensation statement would be: “Company X has set aside funds to compensate you for injuries that are caused by your participation in this research study. These funds will cover the costs of your acute medical care but not the costs of long-term medical care. Company X has not set aside any funds to compensate you for pain or economic harms.” This statement is non-exculpatory, because it specifically refers to Company X’s plans. By accepting this statement, the subject is agreeing only that Company X has these plans; he is not agreeing that he will never receive any compensation from Company X for long-term medical care, pain, or economic harm.¹⁸

A second problem arises in making the compensation-for-injury plan comprehensible by the average research subject. The Common Rule requires that “the information that is given to the subject or the representative shall be in language understandable to the subject or the representative”.¹⁹ Surveys have shown the average informed consent document is written at a 10th grade reading level, even though the reading level of the average subject is 6th to 8th grade level.²⁰ Research also shows that part of the informed consent form describing compensation for injury policies tends to be written at a reading level about one grade higher than the rest of the form.²¹

Compensation-for-injury statements often are grammatically complex and contain legal jargon. Consider the following statement the Crouse Hospital IRB recommends that researchers include when the sponsor has a compensation-for-injury policy:

The above paragraph states the policy of (corporate sponsor). (Corporate sponsor) will make the final determination as to whether any injury suffered during this study is a direct result of the study drug/ procedures. Your physician will provide supporting information but cannot guarantee reimbursement. Neither the researchers nor Crouse Hospital make any representation, warranties or guarantees with respect to the above policy, including either its continued existence or its applicability to yourself should any adverse side effects occur.²²

This policy is very difficult to understand, even for someone with a legal education. It is very difficult for a subject to know, from reading these statements, whether he or she will receive any compensation for research-related injuries. It is likely that the average research subject would pay very little attention to these statements and regard them as incomprehensible legalese.

In their study of compensation for injury policies, Michael Paasche-Orlow and Frederick Brancati found the following passage that rated at a 16th grade reading level:

If physical injury resulting from participation in this research should occur, I understand that, although compensation is not available, medical treatment will be available, including first aid, emergency treatment, and follow-up care as needed, and that my insurance carrier may be billed for the cost of such treatment. I further understand that in making such medical treatment available, or providing it, the persons conducting this research project are not admitting that my injury was their fault.²³

In addition to being difficult to comprehend, this passage contains exculpatory language, namely “compensation is not available,” as well as the potentially coercive phrase “I understand that.”²⁴ Using the phrase “I understand that” in an informed consent document is problematic, because it implies that the subject (or representative) understands (or should understand) something that he or she may not understand.

A third problem arises in administering a compensation-for-injury plan. Suppose the plan will only pay for injuries caused by research participation. Problems arise in determining whether an injury was caused by research participation, the natural progression of the subject’s disease, incompetence or misconduct by the researchers, or the subject’s failure to follow instruction. Sorting through all the possible causes of a subject’s injury can be a very difficult task, especially when subjects are already very ill and the management of their disease is very complex.²⁵

When an outcome may have multiple causes, the substantial factor legal test can be useful.²⁶ Under this test, participation in a research study would be a cause of the subject's injury if participation makes a substantial contribution to the subject's injury. Although the term "substantial contribution" has been criticized as poorly defined, one can use probability theory to define the term more clearly. Under this kind of analysis, causes increase the probability of their effects.²⁷ Thus, the subject's participation in a research study would be a cause of an injury if the participation substantially increased the probability that the injury would occur.

Problems also can arise in deciding who should investigate the injury to determine whether it was caused by research participation. Obviously, the person who carries out the investigation should have expertise in medicine or other disciplines or specialties relevant to the situation. But, who should select the investigator(s)? Should the sponsor of the compensation plan be allowed to hire a physician to carry out these investigations or should the subject name a physician to conduct the investigation? One might argue that the person who decides whether an injury has been caused by the research study should be independent from the research institution and the sponsor, to avoid the potential for bias.

There are many other details that must be ironed out in implementing a compensation plan. These include: deciding whether the plan will provide compensation for psychological harms, such as emotional distress; financing the plan; deciding whether to provide compensation when the subject has payments from collateral sources, such as health insurance; making payments to patients or health care providers; reporting research injuries to IRBs, data and safety monitoring boards, or other entities with

oversight authority; providing information about a person to contact in case of suspected research injury; and establishing an appeal process.

IV. THE VARIETY OF COMPENSATION PLANS

The federal research regulations grant researchers, institutions, and sponsors considerable leeway concerning compensation for research-related injury. As noted earlier, the Common Rule only requires that (a) researchers inform subjects about any compensation plans when the research is more than minimal risk and (b) do not use exculpatory language to describe those these plans during the consent process. Within these minimal constraints, a compensation plan could offer no compensation for injuries, minimal compensation, or generous compensation.

Michael Paasche-Orlow and Frederick Brancati recently published a study on compensation for injury policies adopted by American medical schools. They studied materials available on the Internet from 113 schools and found considerable variation among compensation for injury policies. Thirty-nine percent did not offer coverage for medical bills when the research was sponsored by industry and 78% did not offer coverage for medical bills when there was no industry sponsor. Because about two-thirds of all biomedical research is industry-sponsored, about one-half of research subjects are not offered coverage for medical bills resulting from research-related injuries. Among the schools that offer to cover medical bills when there is no industry sponsor, 50% only offer to cover emergency care. Seventy-two percent of the schools state they do not

provide monetary compensation, and 11% of the schools state that a decision on compensation is a matter of discretion.²⁸

Paasche-Orlow and Brancati also found considerable variation in the language schools used to try to avoid liability for research-related injuries. Nineteen percent state that compensation is unavailable; 16% say compensation is not provided; 10% state compensation is against their policy; 7% say they will not pay for injuries; 4% state they will not offer compensation; and 4% say that have not set aside any funds for compensation. Paasche-Orlow and Brancati also found considerable variation in the readability levels of compensation-for-injury statements in informed consent templates. The reading level varied from 5th grade to 16th grade.²⁹

A survey of materials available on the Internet, which I conducted from February 1 through 7, 2005, found results similar to those report by Paasche-Orlow and Brancati. This Internet survey examined plans from 31 American institutions, using Google. The institutions were included in the survey if they either stated a policy on compensation for research-related injuries or provided researchers with an informed consent template containing compensation-for-injury language. The institutions included public universities, private universities, university medical centers, hospitals, and government medical centers.³⁰

Better understand some of the wording contained in compensation plans, it will be useful to examine some actual plans in more depth. This article discusses nine of the 31 plans in the survey.

A. Cincinnati Children's Hospital Medical Center

Cincinnati Children's Hospital Medical Center (CCHMC), like Crouse Hospital, has a very minimal and noncommittal compensation-for-injury policy. The policy does not offer or promise research subjects any types of compensation for injury. It only provides a number to contact and informs subjects that decisions will be made on an individual basis:

If you believe that you have been injured as a result of participation in biomedical or behavioral research you are to contact [name and telephone number of responsible investigator] or the Director of Social Services...to discuss your concerns. Cincinnati Children's Hospital Medical Center follows a policy of making all decisions concerning compensation and/or medical treatment for physical injuries occurring during or caused by participation in biomedical or behavioral research on an individual basis.³¹

Under this plan, it is possible that the CCHMC could never provide compensation for research injuries, since the institution is not stating any intention to provide any compensation. This plan does not even inform subjects they have a right to seek a legal remedy for compensation. Although the description of the plan does not contain any exculpatory language, it provides subjects with very little guidance or information.

B. National Institutes of Health (NIH), Clinical Center (CC)

The NIH Clinical Center's policy on compensation for research-related-injuries goes a bit further than CCHMC's policy, which promises almost nothing. According to the NIH's policy:

The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have a right to pursue legal remedy if you believe that your injury justifies such action.³²

This policy goes further than CCHMC's because it offers subjects short-term medical care. Although the policy does not explain the phrase "short-term," a reasonable

interpretation would be emergency or acute care or resulting hospitalization. The policy does not make it clear to the subject whether the CC will pay for the costs of such care, since the policy also states the CC will not provide “financial compensation.” This provision could be interpreted to mean the CC will not compensate the subject for the costs of care. Under this interpretation, the CC would be offering to provide care but not pay for it. To avoid this ambiguity, a policy should address whether it will cover the costs of care.

Another problem with the CC’s policy is that it uses exculpatory language. Instead of saying the CC “has no plans” to pay for long-term care or provide financial compensation, the policy states “no long-term care or financial compensation” will be provided. However, the policy attempts to avoid the exculpatory implications of this statement by stating subjects still have a right to pursue a legal remedy.

C. University of California at San Francisco (UCSF)

The University of California at San Francisco’s policy is clearer than the NIH Clinical Center’s policy. According to UCSF’s policy:

If you are injured as a result of being in this study, treatment will be available. The costs of such treatment may be covered by the University of California depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury.³³

This policy, like the CC policy, offers to provide medical treatment. It also brings up the issue of costs for treatment, which the CC’s policy does not, and makes clear that UCSF may cover the costs of treatment. However, the policy also contains exculpatory language, because it says the university and sponsor “do not normally provide any other form of compensation.” This language is exculpatory because it could be interpreted as

releasing the university and sponsor from a legal obligation to provide other forms of compensation. Furthermore, the policy does not contain a statement that the subject still is free to pursue legal remedies. Subjects reading this policy might be led to believe that they can only receive treatment for their injuries.

D. Northwestern University

Northwestern University's compensation-for-injury policy provides more information for research subjects than the policies examined previously. Northwestern uses different statements in the informed consent document, depending on who is sponsoring the research. For research with no external sponsor or sponsored by a federal agency, such as the NIH, the policy states that:

In the event of injury or illness as a result of study medications, devices or procedures, you should seek medical treatment through your physician or treatment center of choice. You should promptly notify the study doctor in the event of any illness or injury. Payment for this treatment will be your responsibility.³⁴

This statement makes it clear that Northwestern is not offering to provide treatment or pay for it. This is a very minimal policy, which offers the subject no help, except to make the obvious recommendation to inform the study doctor and seek treatment.

For research sponsored by industry, Northwestern's policy states:

In the event of injury or illness as a result of study medications, devices or procedures, you should seek medical treatment through your physician or treatment center of choice. You should promptly notify the study doctor in the event of any illness or injury. If you experience an injury or illness as a result of the administration of the study medication (or use of the investigational device, if applicable) or procedures required for this study, the reasonable medical expenses required to treat such injury or illness will be paid for by the study sponsor. The coverage for such injury or illness is only available if the Northwestern University principal investigator (and study sponsor, if appropriate) have determined that the injury/illness is directly related to the study drug (or use of the investigational device, if applicable) or study procedures and is not the

result of a pre-existing condition or the normal progression of your disease, or because you have not followed the directions of the study doctor.³⁵

This policy makes it clear that the study sponsor will compensate subjects for treatment of injuries, but only under certain conditions. To receive coverage, the injury must be caused by research participation, not by the progression of the subject's disease or the subject's failure to follow directions. Although this policy is clear, and does not contain exculpatory language, it probably is difficult for the average research subject to understand.

E. Georgetown University

Georgetown University's compensation for injury policy is very simple and direct:

Researchers will make every effort to prevent study-related injuries and illnesses. If you are injured or become ill while you are in the study, you will receive emergency medical care. The costs of this care will be charged to you or to your health insurer. No funds have been made available by Georgetown University or its affiliates, the District of Columbia, or the Federal government to compensate you for a study-related injury or illness.³⁶

Although the policy only covers emergency medical care, it makes clear to the subject who will pay for this care. Other policies examined in this article, such as the NIH's, do not say who will pay for medical care. The policy also contains no exculpatory language. Instead of saying "Georgetown will not pay" it says "No funds have been made available." Although the policy is fairly minimal, at least it is clear.

F. Veteran Affairs

Since 1998, the Department of Veteran Affairs (VA) has followed a policy of compensating research subjects for injuries. The VA provides and pays for medical care,

unless the injury results from the subject's failure to follow instructions.³⁷ Unfortunately, the informed consent template used by the VA does not clearly state the VA will cover the cost of treatment:

You are participating in a research project approved by a VA Research and Development Committee and conducted under the supervision of one or more VA employees. If you are injured as a result of your participation as a research subject in this research study, the VA medical facility will provide you with necessary medical treatment. EXCEPT that VA will not provide treatment for injuries that result from noncompliance with study procedures.³⁸

G. Virginia Commonwealth University

Virginia Commonwealth University's compensation for injury plan is fairly minimal:

Virginia Commonwealth University and the VCU Health System (formerly known as Medical College of Virginia Hospitals) have no plan for providing long-term care or compensation in the event that you suffer injury as a result of your participation in this research study. If you are injured or if you become ill as a result of your participation in this study, contact your study doctor immediately. Your study doctor will arrange for short-term emergency care or referral if it is needed. Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.³⁹

Although this is a minimal plan, it is not too difficult to understand and contains no exculpatory language. It tells the subject how to get medical care, but also makes clear the subject will be billed for the care.

H. Wake Forest University

Wake Forest University (WFU) has one of the most extensive compensation-for-injury plans among biomedical research institutions. Unlike many institutions, it offers to provide compensation for injuries for studies funded by the government. WFU has two

policies for privately funded research and one policy for research with no private funding.

According to the template for privately funded research on experimental medications:

If you experience an illness, adverse event, or injury that is the result of a medication, intervention, procedure, or test required for this study the sponsor of the study, Sponsor's Name, will pay usual and customary medical fees for reasonable and necessary treatment provided you have not already otherwise been reimbursed by your insurance, a government program, or other third party coverage for such medical expenses. You should notify the study doctor as soon as you believe you have experienced any study related illness, adverse event, or injury. The study doctor and the sponsor will determine if the adverse event or injury was a result of your participation in this study. The sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, your negligence or willful misconduct, or the negligence or willful misconduct of third parties. You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call PI's Name at telephone number (also include after hours number).⁴⁰

While this statement is very thorough, it also is difficult to understand. Even though it contains the phrase "you do not give up any legal rights," it also contains exculpatory phrases like "the sponsor is not responsible." Although it offers more than minimal compensation, it may discourage subjects from seeking compensation, due to its legalistic style.

WFU's template for research on biomedical devices is very similar to the template for medications:

If you experience an illness, adverse event, or injury that is the result of a device, intervention, procedure, or test required for this study the sponsor of the study, Sponsor's Name, maintains product liability insurance coverage and recognizes its responsibility for design and manufacturing defects in products that it designs, manufactures and markets. You should notify the study doctor as soon as you believe you have experienced any study related illness, adverse event, or injury. The study doctor and the sponsor will determine if the adverse event or injury was a result of your participation in this study. The sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, your

negligence or willful misconduct, or the negligence or willful misconduct of third parties. You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call PI's Name at telephone number.⁴¹

This template, like the other, is thorough but difficult to understand. It also contains the exculpatory phrase, "the sponsor is not responsible."

The template for studies with no private sponsor is as follows:

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of \$25,000. The Steadfast Insurance Company provides the insurance policy for this coverage. It provides a maximum of \$25,000 coverage for each claim. The Wake Forest University School of Medicine, and The North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at... You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call PI's Name at telephone number.⁴²

This template, like the others, is thorough, but difficult to understand. It makes clear to patients some of their medical care will be covered if they are injured, and even provides a dollar amount. Although the policy says "you do not give up any legal rights," it also contains the exculpatory phrase "do not assume responsibility."

I, University of Washington

The University of Washington has a compensation for injury plan that it advertises as "no fault." According to the plan, "The University's policy on compensation for adverse effects to human subjects is intended primarily to provide

necessary medical care to subjects who sustain injury as a direct result of experimental interventions conducted as part of an authorized research activity.”⁴³ To qualify for compensation under the plan, the subject’s injuries must not be due to an underlying disease or the subject’s failure to follow study procedures. Moreover, the plan does not offer compensation for mental impairment or emotional distress. Under the compensation plan, subjects do not have to pay for medical care covered by the plan. The research sponsor or the University of Washington will pay for the medical care.⁴⁴

V. PROBLEMS WITH VARIATION AMONG PLANS

The previous section provided evidence for considerable variation in compensation-for-injuries plans (or policies) adopted by research institutions. There is considerable variation in the language used in the plans in terms of complexity, understandability, and use of exculpatory words or phrases. Plans have taken different approaches to the following questions:

A. What Type of Medical Care, If Any, Is Available?

Some plans offer no medical care, some only offer short-term or emergency care, and some long-term or continuing care.

B. Will the Compensation Plan Pay For Any Medical Care?

Some plans do not offer to pay for any medical care, some state the subject or his/her insurance company will be billed for the care, and some state the sponsor will pay for medical care. Some even state the research institution will pay for the care.

C. Will the Compensation Plan Pay For Non-Medical Expenses?

Some plans are silent on this issue. Others mention that there is no intention to pay for non-medical expenses.

D. How Does One Obtain Coverage Under the Plan? Some plans do not answer this question. Others outline specific conditions for obtaining coverage, such as the requirement that the injury is caused by research participation and that one must contact the study doctor.

E. Are Subject Informed That They Still Have Legal Rights to Sue For Compensation?

Some plans address this question. Others do not.

F. Summary

This large variation in the plans should come as little surprise, because the federal research regulations give institutions a great deal of discretion in this area and federal agencies, such as the Office of Human Research Protections (OHRP), offer very little guidance. Given these circumstances, one would expect different institutions would draft different policies, based their different perspectives on the rights and welfare of research subjects and legal risk management issues.

On the one hand, many institutions seek to minimize all legal risks related to biomedical research. These institutions may require other parties, such as sponsors, to compensate subjects for injuries. Institutions that take this approach may require research sponsors to provide indemnification for research-related legal liability and may develop a consent template that contains exculpatory language or attempts to discourage the subject from seeking compensation for injury. On the other hand, some institutions are more concerned about respecting the rights and welfare of research subjects than

about minimizing their own legal risks. These institutions may develop plans to ensure compensation for injury is provided, and that subjects do not have to pay for it. These institutions may develop informed consent templates that do not contain exculpatory language and that clearly explain the subject's rights and recourses.

Are there any problems with variation in compensation-for-injury plans and policies? One might argue that there are no problems with variety. The federal regulations give institutions the flexibility and discretion they require to deal with their ethical and legal responsibilities to research subjects. Any clarification or expansion of the federal regulations relating to compensation for research-related injuries could have a detrimental impact on research. Institutions might adopt defensive practices and policies to minimize their liability risks. They might refrain from participating in risky (but important) studies to avoid compensating subjects for research injuries. A change in the federal regulations could have a chilling effect on IRB deliberations as well. IRBs might base a decision to approve or disapprove a study solely on the study's potential for causing research-related injuries.

This argument for not upsetting the status quo deserves serious consideration, but ultimately it is not convincing. There are two ethical problems related to the injustices inherent in the current system.

First, the current system is unjust because it allows for considerable differences in the treatment of human subjects.⁴⁵ A subject with a research-related injury participating in a study at Wake Forest University will be treated very differently from a subject with an injury participating in a study at Northwestern University. At WFU, an injured subject has some expectation of receiving some treatment for injuries and payment for that

treatment. At Northwestern, a subject does not have these expectations. Even subjects in the same multi-center clinical trial may be treated differently if they are participating at different institutions. Because Cincinnati Children's Hospital and the University of California at San Francisco both make compensation decisions on a case-by-case basis, they might make very different compensation decisions, even under the same set of circumstances by adopting different approaches to subjects' rights and the institution's liability. One might make a counterargument that the subjects in these different institutions are not being treated differently, because they would have the same legal rights to sue for compensation, but this argument misses the point. Most subjects would rather have the assurance they will receive compensation instead of having to endure the stress, hassle, and uncertainty of filing a lawsuit.

The wide variation of compensation-for-injury plans violates the formal principle of justice, because two research subjects could have the same type of injury, under the same circumstances, yet receive different treatment based on ethically irrelevant factors. The formal principle of justice imposes a consistency standard on ethical decision making: similar cases should be treated similarly.⁴⁶ If two people commit the same crime and have the same aggravating or mitigating factors, they should receive the same punishment. If two employees perform the same type of work and have the same experience, they should receive roughly the same pay. Differential treatment of people, especially research subjects, without a good reason is patently unfair. To correct this situation, steps should be taken to standardize compensation for injury plans and policies. According to Vasgird, "[Compensation for injury] is such a fundamental and

extraordinarily important ethical requirement that it should be federally mandated and not left to the inconsistent discretion of individual IRBs.”⁴⁷

A second reason the current system is unjust is that it permits the benefits and burdens of research to be distributed unfairly. Private sponsors benefit from the profits they earn selling biomedical products, such as drugs or medical devices. Research institutions benefit from the contracts and grants they receive from private or government sponsors to conduct research, which compensate institutions for the direct and indirect costs of doing research. Institutions can use direct costs to purchase equipment or hire untenured (soft money) faculty or staff. They can use indirect costs to pay for research administration, library resources, or other overhead expenses.⁴⁸

Research subjects also often benefit from research, because they may receive medical or other therapy, educational materials, or money. However, if a subject is injured in research, the burdens for that subject may far outweigh the benefits. To reduce the subject’s burdens, the other parties who benefit from research, .i.e. sponsors and institutions, should make provisions to ensure that the subject receives appropriate compensation, such as medical treatment, for any injury.

Under the current system, neither sponsors nor institutions are required to provide any compensation to subjects for research-related injuries. In some situations, the subject’s insurance company may cover the cost of treatment, but this is not always the case. Some insurance companies refuse to pay for this medical care, and, more importantly, many subjects may not have health insurance.⁴⁹ About 15.6% of the United States population lacks health insurance.⁵⁰ As previously noted, about one half of research subjects are not offered any compensation for medical bills. Under the current

system, many research subjects bear the full financial burden of research-related related injuries without any compensation from parties who benefit from research. A system that allows this to occur is unjust.

VI. SOLUTIONS

What should be done about the prevailing injustices in the current American system of compensating subjects for research-related injuries? One solution has been on the table for at least twenty years: adopt a no-fault system for compensating research subjects. The President's Commission recommended the research community experiment with a no-fault system to determine whether it would be feasible and effective.⁵⁰ Under a no-fault system, a medical expert would review each case to determine whether there was an injury that qualifies for compensation and the injury was caused by research participation. The expert would not make a decision based on the assignment of blame, but only on the assignment of causation. Subjects would not receive compensation for injuries caused by an underlying illness, but only for injuries caused by their participation in research.

A no-fault plan could provide coverage for short-term medical care, long-term medical care, and economic losses. The plan would have mechanisms for reimbursing providers or subjects, and could include limitations on payments. The plan would be financed by the parties who benefit from research, such as research institutions, private sponsors, and government agencies. The plan would cover only research that has been reviewed and approved by an appropriate IRB. It would require a system for appealing

compensation decisions. If a subject were dissatisfied with compensation under the plan, he or she still would be free to file a lawsuit against the responsible parties. However, if a subject brought a lawsuit before submitting his or her case to the plan, then that subject would be ineligible for compensation under the plan.⁵²

There are many advantages of no-fault compensation for injuries. First, a no-fault system encourages open communication, cooperation, and trust among the parties because it does not assign fault. The tort system has the opposite effect, because it makes the parties into legal adversaries.⁵³ By encouraging open communication, a no-fault system also may help researchers and institutions develop systems and procedures for preventing research-related injuries.

Second, a no-fault system tends to be fairer than the tort system, because it ensures that every injured person receives some compensation. Under the tort system, only people who can successfully sue or achieve a settlement receive compensation for injuries. This approach resembles a lottery because it produces a few big winners but many losers.⁵⁴ Third, a no-fault system may help reduce the amount of litigation related to biomedical research. This could have many beneficial effects, such as reducing insurance costs and legal fees, as well as defensive practices.

Many of the compensation plans adopted by research institutions could be regarded as quasi-“no-fault” plans, in that they award compensation based on causation, not negligence. For instance, the plans adopted by the VA and the University of Washington could be regarded as “no-fault” because they provide compensation for injuries caused by research participation.⁵⁵ However, these plans usually do not award compensation for injuries caused by the participant’s failure to follow instructions. Thus,

they are not pure no-fault plans, because they address the issue of fault through the analysis of causation.

If no-fault plans have been discussed for over two decades and they have some distinct advantages, then why have they not met with more widespread support in the United States? A major reason no-fault systems are not popular in the United States is that institutions and sponsors do not want to bear the burden of financing these plans.⁵⁶ Even though no-fault systems can save money, they also can cost a great deal of money. A no-fault plan may help reduce the number of large awards to subjects only at the expense of increasing the number of small awards. It also costs a great deal of money to properly administer a no-fault plan, especially since people are likely to submit fraudulent claims or game the system.

To make a no-fault system work, research institutions, health insurers, and sponsors would need to find a way of sharing the costs of a compensation plan. To do this, the parties involved in funding the plan must agree on important details, such the design of the system, and its financial and administrative operation.⁵⁷ These agreements may not be easy to achieve.

Furthermore, no-fault systems for biomedical research may be difficult to implement and sustain when a fault system for the rest of biomedicine remains in place. A person who is injured in research may be able to recover money both from the no-fault plan, which applies only to research, and from a medical malpractice lawsuit for injuries caused by medical treatment. Because a subject (or patient) still could recover damages through the tort system, adopting a no-fault system for research might not significantly improve trust or decrease litigiousness in medicine research. Some countries, notably

New Zealand and Sweden, have adopted no-fault systems for medical injuries.⁵⁸ If the United States does not follow their example, a no-fault system that applies only to medical research is not likely to be successful.

Finally, for a no-fault system to work effectively, participants in the plan must agree not to bring a tort action against the parties covered by the plan, because the plan will be too expensive if participants still can easily seek compensation through the tort system.⁵⁹ A research subject who agrees to participate in the plan must prove his or her waiver of tort remedies was invalid, to bring tort litigation against the parties included in the plan. The participant could attempt to prove, for example, lack of sufficient mental capacity to consent to the plan or a failure to understand the agreement.

In any case, a no-fault plan requires participants to forfeit some of their legal rights, a requirement that conflicts with the Common Rule's prohibition against exculpatory language in informed consent. Unless the federal government eliminates this prohibition the next time it revises the Common Rule, the requirement that informed consent contain no exculpatory language serves as a roadblock to an effective no-fault system.

One way to get around this roadblock would be to ask subjects to provide two different consents: consent to participate in the study and consent to participate in the no-fault compensation plan. Although this idea seems workable in theory, it might be difficult to implement in practice. Subjects might not realize that they can participate in the study without participating in the no-fault plan, especially if researchers present them with two different consent documents at the same time. Additionally, asking subjects to consent to the plan raises the question of who would review the no-fault consent forms.

These forms would have important implications for the rights and welfare of human subjects, but IRBs would not be authorized to review them.

In theory, a no-fault system for compensating subjects for research-related injuries could work in the United States. However, major changes in the American health system would have to occur, including the development of regulations to promote standards for no-fault systems, dropping the prohibition against exculpatory language in the informed consent process, coordination of efforts among different parties, and the adoption of a no-fault system in the rest of medical practice. Given the current state of the American health care system and surrounding legal climate, these changes are not likely to occur any time soon. A no-fault system may be an attractive option for compensating research subjects in other countries, but it probably is not a viable option in the United States.

Even though a no-fault system for biomedical research is not a viable option in the U.S, there are two other more viable ways of correcting the injustices found in the United State's system for compensating subjects for research-related injuries. First, government agencies, such as the FDA and NIH, should adopt uniform regulations (and interpretive guidance) dealing with compensation for injuries as an amendment to the Common Rule. The regulations should require IRBs to withhold approval from research studies classified as more than minimal risk if those studies do not have a plan to compensate subjects for research-related injuries. The regulations should set minimum standards for compensation plans. As a minimum standard of fairness, research institutions should ensure that subjects will not have to pay for medical treatment of

research-related injuries. Institutions should pay for necessary treatment not covered by the research sponsors or the subjects' own health insurance.

Plans also should establish procedures for expert review of reports of research-related injuries, as well as procedures for appealing reviewers' decisions. The plans could take fault into account when making compensation decisions. For example, the plans could decline to pay for injuries caused by the subject's failure to comply with procedures or the researchers' misconduct or gross negligence. Finally, the plans should be consistent with the informed consent requirements already found in the Common Rule, such as the prohibition on exculpatory language.

Admittedly, amending the Common Rule is easier said than done: political obstacles may stand in the way of any substantive changes to this set of regulations. Research institutions and sponsors may actively oppose any changes to federal policy likely to increase the cost of biomedical research. However, it is possible to overcome this opposition with sufficient popular support for change. 45 C.F.R. part 46 has been amended several times since it was adopted in 1981. There is no reason it cannot or should not be amended again.

As a second way of solving injustices in the current system, organizations that promote ethics in clinical research, such as the Association of Clinical Research Professionals (ACRP) and Public Responsibility in Medicine & Research (PRIM&R), should develop standards (or best practices) for compensation-for-injury plans. These organizations should use these standards for certifying IRBs. Even though certification is not a legal requirement for operating an IRB, it can exert a great deal of influence over

research practices and policies, because many research institutions and sponsors regard certification as a worthy goal.

CONCLUSION

The current system of compensation for research-related injuries in the United States is unjust because it allows for inconsistent treatment of human subjects and does not require research institutions or sponsors to compensate subjects for research-related injuries. To correct the injustices in this system, the federal government should revise the human research regulations to set a minimum standard for compensation plans. In addition, organizations that promote ethics in clinical research should develop standards for compensation plans.

NOTES

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⁵⁹ *Id.*