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Research-Related Injury Compensation Policies of U.S. Research Institutions

David B. Resnik, JD, PhD[*],
National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC

Efthimios Parasidis, JD, MBE,
Moritz College of Law and the College of Public Health, Ohio State University, Columbus, OH

Kelly Carroll, JD, MBE,
Washington, DC

Jennifer M. Evans, JD,
Raleigh, NC

Elizabeth R. Pike, JD, LLM, and
Presidential Commission for the Study of Bioethical Issues, Washington, DC

Grace E. Kissling, PhD
National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, NC

Abstract

Federal research regulations require participants to be informed about whether medical care or compensation for injury is available in more than minimal risk studies and prohibit language in informed consent documents that waives, or appears to waive, legal rights. The objectives of this study were to compare data collected in 2000 and 2012 to identify significant changes in types of institutional compensation policies at U.S. research institutions, and assess the relationship between institutional characteristics and different types of policies. We found that research-related injury compensation policies did not change substantially during the time period. A significant percentage of policies contain language that can be reasonably interpreted as waiving, or appearing to waive, legal rights. Level of funding, public vs. private status, and institutional involvement in clinical research were associated with different types of policies. The lack of substantial change in compensation policies supports arguments for a national policy.

Introduction

Human volunteers are sometimes injured as a result of their participation in research. Though most injuries are minor, some injuries result in hospitalization, long-term disability, or, in rare cases, death.[1] Participants may be required to pay for their medical care if they

[*]Corresponding author. NIEHS/NIH, 111 Alexander Drive, Box 12233, Mail Drop CU 03, Research Triangle Park, NC, 27709, USA. resnikd@niehs.nih.gov.

lack health insurance or if the insurance company, institution, or sponsor will not cover the costs of care. Participants may also suffer economic and non-economic harms as a result of their injuries, such as lost wages, pain and suffering, or missed opportunities for employment.[2] Many U.S. research institutions and sponsors have adopted policies for compensating injured research participants.[3,4] These policies can help remedy harms to individuals and minimize litigation, but can also vary considerably.[3-5] Individuals with the same research-related injuries in a multicenter study may ultimately receive different remedies if they participate at different institutions. Although federal research regulations do not mandate compensation for research-related injuries, they require that participants be informed of the availability of medical care or compensation for injury (if any) for more than minimal risk research.[6,7] Regulations also prohibit informed consent from including any exculpatory language in which the participant (or his or her representative) waives or appears to waive legal rights, or releases or appears to release the investigator, institution, or sponsor from liability for negligence.[8,9]

To inform the public debate about this issue, it is important to have up-to-date information concerning policies adopted by U.S. research institutions. Efthimios Parasidis (EP), a co-author, published a 2000 study on compensation policies from 127 institutions.[5] More than a third of the institutions surveyed offered no compensation for research-related injuries, and 42% offered compensation only at the discretion of the institution or sponsor.[5] However, these data are more than ten years old, and the research environment has changed since then as a result of increased legal liability risks related to oversight by federal agencies or lawsuits from injured participants. At the same time, the risks inherent to the research have increased as, for instance, companies are conducting innovative research related to gene therapy, nanomedicine, and the development of biologics and new molecular entities. In 2005, the Lewin Group prepared a report for the Department of Health and Human Services on care and compensation for injuries in clinical research.[10] The report identified 129 policies from 102 research institutions and found that the vast majority offered no compensation for injuries. Although this report offers some useful information, it lacked scientific rigor. For example, the sampling method and coding procedures were not well-defined, no statistical methods were used, and the report was not published in the open literature.[10]

The aim of our study was to conduct a rigorous description and analysis of research-related injury compensation policies at U.S. research institutions by (1) comparing data from 2000 and 2012 to identify any significant changes in types of compensation policies, and (2) determining whether institutional characteristics are associated with different types of policies. Though our analysis focused on compensation for medical care, we also tried to determine whether policies address compensation for more than medical care.

Methods

We worked with two datasets, one from EP's study and one collected for the current (2012) study. EP provided us with documents from his study, which he performed with help from Jon Merz. EP emailed members of MCWIRB (a discussion forum for individuals involved in oversight of human subjects research now known as IRB Forum) a survey on March 2,

2000, with two reminder emails. Eighty-nine out of 349 email recipients responded via email or fax. To obtain additional data, the websites of the top 100 National Institutes of Health (NIH)-funded institutions for fiscal year 1999 were examined. Sixty of these institutions had information available on their webpages. After eliminating overlap between emails and websites, EP's study included data from 127 institutions.

For our current study, we attempted to access policies from the top 200 funded U.S. research institutions according to the most recent data available through the Center for Measuring University Performance (CMUP).[11] We used the CMUP list because the MCWIRB email list has changed considerably in 12 years, and the top 200 institutions on the CMUP list include most of the top 100 NIH-funded institutions. We eliminated one institution, University of California (UC) Central Administration, from the list because it does not conduct research with human subjects, although specific schools within the UC system—which were included—do.

We first attempted to access policies through publicly available websites. We defined a compensation policy as language contained in institutional documents, such as informed consent templates or standard operating procedures, which provide official guidance concerning compensation for research-related injuries. When language in the consent template conflicted with other sources of policy, we gave preference to the template; if a participant sued for damages, the consent document could be crucial in determining liability.[3] If we were unable to obtain policies on publicly available websites, we sent an email to institutional representatives, such as Institutional Review Board (IRB) chairs or IRB managers, asking them for a copy of institutional policies. We sent two reminder emails if we received no response.

We coded compensation language based on a classification scheme developed for this study. We recoded data from EP's earlier study using our new coding scheme. We developed the coding scheme after reviewing the EP's study and examining about half the data from our current study. We also consulted Office of Human Research Protections (OHRP) guidance on exculpatory language.[12] Compensation was defined as, at a minimum, payment for immediate medical care. Many institutions offer to provide immediate medical care, but this is not the same as paying for it. For our purposes, we were interested in determining whether institutions would pay for medical care, since participants may face tremendous burdens if required to pay for medical care themselves.

We developed four models of compensation offers (No Compensation, Discretional Compensation, Conditional Compensation, and Unconditional Compensation) and three models of exculpatory language (Not Exculpatory, Potentially Exculpatory, and Exculpatory) that correspond to conceptually distinct categories (see Box 1 and Box 2 for definitions and examples). We also collected other data pertaining to policies, such as whether policies offer different options for compensation language and whether there was an offer to provide compensation beyond payment for immediate medical care.

To ensure consistency, policies were coded independently by two people (JE and KC), who received training in our coding procedure. Inter-rater agreement was assessed using kappa statistics, and differences in coding were reconciled by a conference with the study team.

In addition to gathering data on compensation policies, we obtained data on five institutional characteristics: NIH funding amount and rank, public vs. private status, geographical region, and involvement in clinical research for responding and non-responding institutions. An institution was classified as involved in clinical research if it was a medical school or was associated with one, was a health care institution (such as a hospital), or was a contract research organization that conducts or manages clinical trials. For example, Johns Hopkins University would be classified as involved in clinical research because it has a medical school. Institutions not involved in clinical research included universities or colleges that are not associated with a medical school. For example, Massachusetts Institute of Technology would be classified as not involved in clinical research. Institutions not involved in clinical research might still have a compensation-for-injury policy because they might be conducting non-clinical research that entails more than minimal risks, such as studies of human physiology that involve muscle biopsies or cardiac stress tests.

To establish generalizability of the findings, we compared responders to non-responders regarding institutional characteristics. We used Mann-Whitney tests for NIH funding and rank, which were not normally distributed. We compared the other institutional characteristics, which were categorical, using chi-square tests.

Among the respondents, further analyses compared 2000 and 2012 responses. Because some institutions responded in 2000 and 2012 while others responded only once, we conducted these analyses in two phases. Phase 1 compared 2000 responders to 2012 responders without regard to whether institutions responded both times using Mann-Whitney tests for NIH funding and rank, and chi-square tests for all other measures. Phase 2 compared only those that responded both in 2000 and 2012. Because these measurements were likely correlated, we used statistical methods for paired data. In particular, we used Wilcoxon signed ranks tests to compare NIH funding and rank between the two time points. For categorical measures, we determined the percentage of institutions that changed categories from 2000 to 2012 and tested these percentages for significance using binomial tests for proportions.

For the 2012 institutions, we investigated associations between institutional characteristics and types of compensation policies using chi-square statistics or Fisher's exact test. Fisher's exact test was used if one or more expected frequencies were less than five. For these analyses, NIH funding, NIH funding rank, total funding and national rank were categorized into quartiles; institutions having no NIH funding or NIH funding rank were placed into a fifth separate category (Unfunded or Unranked, respectively).

All p-values were two-sided and any less than 0.05 were considered statistically significant. SAS 9.2 (2008, SAS Institute, Cary NC) statistical software was used for data analysis.

Our current study was reviewed by the NIH's Office of Human Subjects Research Protections, which determined that the federal research regulations do not apply to this study, since we were not collecting private information about individuals. EP's study was

approved by the University of Pennsylvania Committee on Studies Involving Human Beings.

Results

Table 1 summarizes institutional characteristics for 2000 and 2012 data. The response rate for 2000 was 127/372 (34.1%) and 2012 was 169/199 (84.9%). The main reason for the different responses rates is that most of the 2012 data came from publicly available websites, whereas most of the 2000 data came from email responses. The two raters had perfect agreement in coding the type of compensation offered; there was disagreement concerning coding of exculpatory language (kappa statistic p-value < 0.001). The raters disagreed on 36 of the 177 institutions (20.3%). Consensus ratings from members of the research team were used in the statistical analyses.

Compensation Offered

A comparison of 2000 and 2012 data using Fisher's exact test yielded no statistically significant differences in type of compensation offered (see Figure 1). The percentage of institutions offering no compensation was 56.1% in 2000 and 51.2% in 2012; discretionary compensation was 11.2% in 2000 and 8.1% in 2012; conditional compensation was 31.8% in 2000 and 36.9% in 2012; and compensation without conditions was 0.9% in 2000 and 3.8% in 2012. When the analysis focused on the 57 institutions that responded both in 2000 and 2012, the only significant change is that 9.1% changed from no compensation in 2000 to discretionary compensation in 2012 ($p < 0.001$). No institutions in 2000 and only two institutions in 2012 (1.2%) offered compensation beyond payment for immediate medical care.

Exculpatory Language

A comparison of 2000 and 2012 data using Fisher's exact test yielded no statistically significant differences in exculpatory language (see Figure 2). The percentage of institutions with no exculpatory language was 66.4% in 2000 and 78.4% in 2012; potentially exculpatory language was 32.7% in 2000 and 21.2% in 2012; and exculpatory language was 0.9% in 2000 and 0.6% in 2012. When the analysis focused on institutions that responded in 2000 and 2012, the only significant change is that 10.9% changed from no exculpatory language in 2000 to potentially exculpatory language in 2012 ($p < 0.001$).

Associations with Institutional Characteristics

We focused on 2012 data to determine whether types of compensation policies are associated with institutional characteristics. NIH funding was significantly associated with the type of compensation offered. For example, among the top ranked institutions, only 12.2% offered no compensation, as compared to 46.3% for the second quartile, 63.2% for the third quartile, 86.1% for fourth quartile, and 75% for unranked ($p < 0.001$). We found similar differences related to funding when we looked at total NIH funding instead of NIH ranking (see Table 2). Institutional control was significantly associated with the type of compensation offered. For example, 33.3% of private institutions offered no compensation, as compared to 57% of public institutions ($p < 0.013$). Involvement in clinical research also

was significantly associated with the type of compensation offered. For example, 32% of institutions involved in clinical research offered no compensation, as compared to 80.9% not involved in clinical research ($p < 0.001$). (See Table 2.).

Discussion

Our most important finding is that there have been no substantial changes in research-related injury compensation policies among U.S. institutions since 2000. More than half of U.S. research institutions currently offer no compensation for research-related injuries and less than 5% offer unconditional compensation. Other important findings are that more than 20% of institutions include potentially exculpatory language in consent forms, and 10.9% of institutions changed from no exculpatory language in 2000 to potentially exculpatory language in 2012. Regardless of whether the forms ultimately would be deemed by a court to violate federal regulations, the forms are ethically problematic because they may lead research participants to mistakenly believe that they have no right to sue research institutions or sponsors for damages.

The lack of substantial change in institutional policies during this period suggests that significant changes are unlikely to occur without additional government pressure, such as legislation or administrative rule-making. The persistence of the status quo concerning research-related injury compensation policies adds urgency to arguments in favor of a national system. Since other writers [3,4] have made the case for a national system, we will not discuss that option here.

Another important finding is that institutional characteristics were associated with different types of policies. Some possible explanations of these associations are that top NIH-funded institutions and institutions involved in clinical research may be more likely to conduct research that exposes subjects to significant risks and may therefore be more likely to develop policies to address research-related injuries. Private institutions may have more of an incentive to develop compensation for injury policies than public ones because they face greater legal risks, given existing legal barriers to suing public institutions. However, these are speculative hypotheses, and more research is needed on the factors that influence policy development.

It is worth noting that institutional practices for compensating research subjects for injuries may diverge from institutional policies because some institutions may ultimately offer compensation even if their policy does not promise it.[5] Institutions may provide compensation on an ad hoc basis to avoid lawsuits or adverse publicity, or out of compassion for injured participants. To better understand these issues, it may be useful to conduct future studies on institutional practices and participants' experiences with compensation.

Our study has some potential limitations. First, the response rate for the EP study was somewhat low, which could have led to a response bias. We compared responders and non-responders for the 2000 data and found that responders received more NIH funding and were ranked better. In addition, a higher percentage of responding institutions were involved

in clinical research. However, institutional control, and geographic region were similar between responders and non-responders. These differences may somewhat limit generalizability of the 2000 findings. The response rate for the 2012 study was high, and a comparison of responders and non-responders found no significant differences, which bodes well for the generalizability of these findings.

Sample size is another potential limitation of our study. With a larger sample size, we may have been able to detect statistically significant relationships not found in this sample. Nevertheless, we believe that the sample was large enough to draw some useful conclusions about compensation policies at U.S. institutions.

Conclusion

Research-related injury compensation policies at U.S. research institutions have changed very little since 2000. The lack of substantial change in the last dozen years suggests that changes are not likely to occur in the future without additional government pressure. Policymakers should consider taking steps toward developing a national policy for compensating injured research subjects, and institutions should take immediate steps to ensure that their informed consent documents do not include language that waives, or appears to waive, legal rights.

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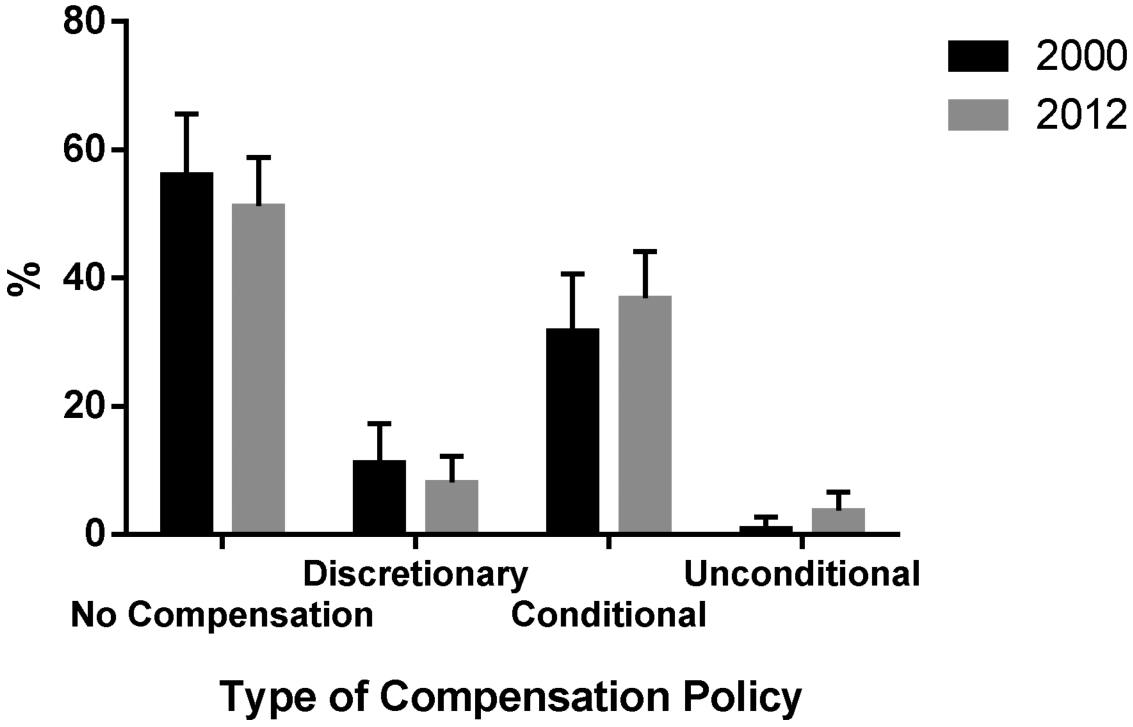

Figure 1.

This figure shows the percentages of institutions in the 2000 and 2012 samples having each of the four types of compensation policies. Error bars represent 95% confidence intervals for the percentages. The distribution of institutions among the four policy types in 2012 was not significantly different from that in 2000 (Fisher's exact p-value = 0.38).

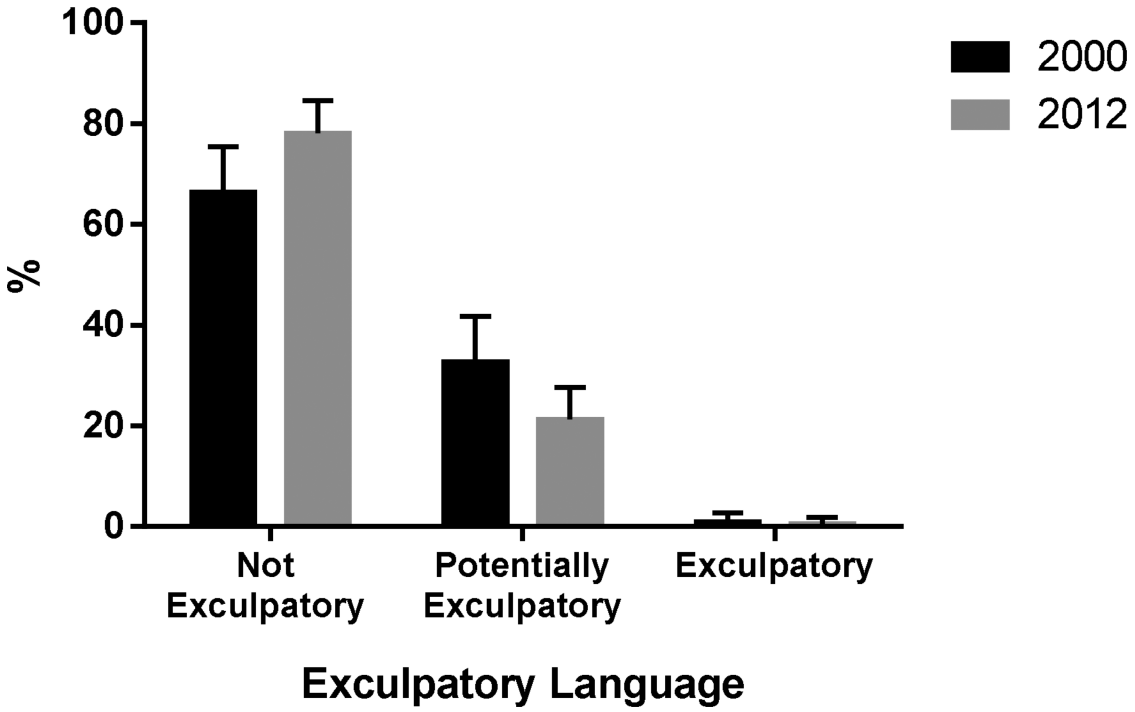

Figure 2.

This figure shows the percentages of institutions in the 2000 and 2012 samples having each of the three categories of exculpatory language. Error bars represent 95% confidence intervals for the percentages. The distribution of institutions among the three categories in 2012 was not significantly different from that in 2000 (Fisher's exact p-value = 0.063).

Table 1

Characteristics of all institutions, including responders and nonresponders

	2000		2012	
	Responded in 2000 (n = 127)	**Did not respond in 2000 (n = 245)**	**Responded in 2012 (n = 169)**	**Did not respond in 2012 (n = 30)**
	Mean ± S.D. (n)	**Mean ± S.D. (n)**	**Mean ± S.D. (n)**	**Mean ± S.D. (n)**
NIH funding (× 10^6)	$54.10 ± $73.44 (127)	$13.69 ± $28.44*** (245)	$82.83 ± $120.41 (169)	$67.59 ± $88.17 (30)
NIH funding rank	246 ± 433 (102)	490 ± 599*** (164)	229 ± 285 (164)	183 ± 166 (28)
Unranked (NIH)	25 (19.7%)	81 (33.1%)**	5 (3.0%)	2 (6.7%)
Total research funding (× 10^6)			$248.07 ± $239.96 (169)	$230.99 ± $154.08 (30)
National rank			101 ± 58 (169)	96 ± 57 (30)

		Frequency (%)	**Frequency (%)**	**Frequency (%)**	**Frequency (%)**
Institutional control	Private	63 (49.6%)	147 (60.0%)	40 (23.7%)	11 (36.7%)
	Public	64 (50.4%)	98 (40.0%)	129 (76.3%)	19 (63.3%)
Human subjects research	Yes	127(100.0%)	36 (14.7%)	169 (100.0%)	30 (100.0%)
	Missing		209 (85.3%)		
Geographic region	Midwest	28 (22.0%)	61 (24.9%)	32 (18.9%)	7 (23.3%)
	Northeast	42 (33.1%)	60 (24.5%)	40 (23.7%)	6 (20.0%)
	South	36 (28.4%)	78 (31.8%)	63 (37.3%)	10 (33.3%)
	West	21 (16.5%)	46 (18.8%)	34 (20.1%)	7 (23.3%)
Involved in clinical research	Yes	95 (75.4%)	133 (54.3%)***	100 (59.2%)	12 (40.0%)
	No	31 (24.6%)	112 (45.7%)	69 (40.8%)	18 (60.0%)

* Nonresponders differ from responders at $p < 0.05$

** $p < 0.01$

*** $p < 0.001$

Table 2

Associations of 2012 institutional characteristics with type of compensation policy.

		Type of Compensation Policy				
	n	**No Compensation**	**Discretionary**	**Conditional**	**Unconditional**	**p-value**
NIH Ranking						
First quartile	41	5 (12.2%)	7 (17.1%)	25 (61.0%)	4 (9.8%)	<0.0001
Second quartile	41	19 (46.3%)	2 (4.9%)	19 (46.3%)	1 (2.4%)	
Third quartile	38	24 (63.2%)	2 (5.3%)	12 (31.6%)	0 (0.0%)	
Fourth quartile	36	31 (86.1%)	2 (5.6%)	2 (5.6%)	1 (2.8%)	
Unranked	4	3 (75.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	
Total NIH Funding (× $10^6)						
None	4	3 (75.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	<0.0001
< 9.17	36	31 (86.1%)	2 (5.6%)	2 (5.6%)	1 (2.8%)	
9.17 – 36.20	38	24 (63.2%)	2 (5.3%)	12 (31.6%)	0 (0.0%)	
36.20 – 107.7	41	19 (46.3%)	2 (4.9%)	19 (46.3%)	1 (2.4%)	
≥ 107.7	41	5 (12.2%)	7 (17.1%)	25 (61.0%)	4 (9.8%)	
Institutional Control						
Private	39	13 (33.3%)	4 (10.3%)	18 (46.2%)	4 (10.3%)	0.0130
Public	121	69 (57.0%)	9 (7.4%)	41 (33.9%)	2 (1.6%)	
Involved in Clinical Research						
Yes	97	31 (32.0%)	9 (9.3%)	52 (53.6%)	5 (5.2%)	<0.0001
No	63	51 (80.9%)	4 (6.4%)	7 (11.1%)	1 (1.6%)	

Notes: n = Number of institutions. P-values are from Fisher's exact tests. Total NIH Funding is divided into quartiles.

Box 1

COMPENSATION LANGUAGE			
Model	**Definition**	**Parameters**	**Example**
No Compensation	The consent form or policy does not state that compensation will be provided.	Policies were coded as **No Compensation** if there was no mention of compensation; if the informed consent form said that no compensation is offered, planned for, or provided; if the form included a place to insert sponsor language without specifying what the sponsor must do; or if the institution offered to provide care but not pay for it.	"All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University [omitted] has not set aside funds to pay you for any such reactions or injuries, or for the related medical care."
Discretionary Compensation	The consent form or policy states that compensation is at the discretion of the institution/sponsor.	Policies were coded as **Discretionary Compensation** if they stated that compensation is provided at the discretion of the institution or sponsor, or that compensation may be, could be, or might be provided. We treated the words "may," "could," and "might" as discretionary terms because they do not express a definite commitment to provide compensation.	"If you are injured or harmed as a result of participating in the study and receive medical care through the [omitted], a [omitted] doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance. If this medical care is provided by [omitted] or by a [omitted] doctor, the study sponsor may pay these providers for any reasonable medical expenses to treat your injury. The study sponsor, however, is not offering to pay for medical expenses that are covered by your insurance provider or if your injury was not caused by the study drug/device or a study procedure."
Conditional Compensation	The consent form or policy states that compensation will be provided if specific conditions are met.	Policies were coded as **Conditional Compensation** if they included conditions that must be fulfilled for the participant to obtain compensation (other than the injury was caused by research). Some of these conditions included: the patient does not have insurance or the insurance company will not pay; there is an agreement with the sponsor to provide compensation; and the patient agrees to receive care at the institution.	[Language to use if there is a commercial sponsor]: "All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researcher will help you get medical care, but The University [omitted] has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. The Sponsor of the study, [INSERT SPONSOR NAME], has agreed to pay all reasonable medical expenses for the treatment of injuries related to the administration of the study drug/device, defects in the manufacture of the study drug/device, or as a direct result of properly performed study procedures. The Sponsor will not pay for the treatment of any underlying disease or condition that you may have. Any costs for medical expenses not paid by the Sponsor will be billed to you or your insurance company. However, by signing this form, you do not give up any of your legal rights."
Unconditional Compensation	The consent form or policy states that compensation will be provided without discretion or conditions.	Policies were coded as **Unconditional Compensation** if they stated that compensation will be paid for (as opposed to might be paid for) and they did not include any specific conditions other than the injury is research related.	"If you are injured or have any harmful effects as a direct result of your being in this research, treatment will be made available to you at [omitted]. You will not have to pay any charges resulting from the harmful effect or injury of a study drug (or device) or procedure that would not have otherwise been done as part of your regular care."

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Box 2

EXCULPATION LANGUAGE			
Model	**Definition**	**Parameters**	**Example**
Not Exculpatory	The consent form or policy does not include language that waives or appears to waive legal rights.	Policies were coded as **Not Exculpatory** if they said nothing that could be reasonably interpreted as waiving legal rights or if they explicitly stated "by signing this form you do not waive legal rights" (or similar wording).	"In the unlikely event you become injured as a result of your participation in this study, medical care is available. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury. By signing this document, you are not waiving any rights that you have against [omitted] University for injury resulting from negligence of the University or its investigators."
Potentially Exculpatory	The consent form or policy includes language that may be reasonable interpreted to limit legal rights.	Policies were coded as **Potentially Exculpatory** if they included language that might reasonably be interpreted as waiving legal rights, such as "the institution will not pay," "the institution does not normally provide compensation," or "the institution has not set aside funds for compensation." Since these clauses were written in legal terminology (not in plain language), we used the perspective of the reasonable attorney to define the phrase "reasonably interpreted."	"In accordance with Federal regulations, we are obligated to inform you about [omitted]'s policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from [omitted]....You should not expect anyone to pay you for pain, worry, lost income, or non-medical care costs that occur from taking part in this research study."
Exculpatory	The consent form or policy includes language that explicitly waives some legal rights.	Policies were coded as **Exculpatory** if they included an explicit waiver of legal rights, such as including phrases like "by signing this form, you agree not to sue the institution" or "you release the institution from liability for negligence."	"I agree that all known risks to me have been explained to my satisfaction and I understand that no compensation is available from [omitted] University and its employees for any injury resulting from my participation in this research."