HEALTH POLICY

Effects of Disclosing Financial Interests on Attitudes Toward Clinical Research

Kevin P. Weinfurt, PhD[1,2], Mark A. Hall, JD[3,4], Michaela A. Dinan, BS[1], Venita DePuy, MStat[1], Joëlle Y. Friedman, MPA[1], Jennifer S. Allsbrook, BSPH[1], and Jeremy Sugarman, MD, MPH, MA[5]

[1]Center for Clinical and Genetic Economics, Duke Clinical Research Institute, Duke University School of Medicine, Durham, NC, USA; [2]Department of Psychiatry and Behavioral Sciences, Duke University School of Medicine, Durham, NC, USA; [3]Wake Forest University School of Law, Winston-Salem, NC, USA; [4]Wake Forest University School of Medicine, Winston-Salem, NC, USA; [5]Berman Institute of Bioethics and the Department of Medicine, The Johns Hopkins University, Baltimore, MD, USA.

BACKGROUND: The effects of disclosing financial interests to potential research participants are not well understood.

OBJECTIVE: To examine the effects of financial interest disclosures on potential research participants' attitudes toward clinical research.

DESIGN AND PARTICIPANTS: Computerized experiment conducted with 3,623 adults in the United States with either diabetes mellitus or asthma, grouped by lesser and greater severity. Respondents read a description of a hypothetical clinical trial relevant to their diagnosis that included a financial disclosure statement. Respondents received 1 of 5 disclosure statements.

MEASUREMENTS: Willingness to participate in the hypothetical clinical trial, relative importance of information about the financial interest, change in trust after reading the disclosure statement, surprise regarding the financial interest, and perceived effect of the financial interest on the quality of the clinical trial.

RESULTS: Willingness to participate in the hypothetical clinical trial did not differ substantially among the types of financial disclosures. Respondents viewed the disclosed information as less important than other factors in deciding to participate. Disclosures were associated with some respondents trusting the researchers less, although trust among some respondents increased. Most respondents were not surprised to learn of financial interests. Researchers owning equity were viewed as more troubling than researchers who were compensated for the costs of research through per capita payments.

CONCLUSIONS: Aside from a researcher holding an equity interest, the disclosure to potential research participants of financial interests in research, as recommended in recent policies, is unlikely to affect willingness to participate in research.

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INTRODUCTION

Clinical research involves increasingly complex financial relationships among investigators, site personnel, research institutions, and industry. Commentators have raised concerns about the financial conflicts of interest that can arise in such circumstances.[1–5] Prominent among the many options discussed for managing conflicts of interest is that financial relationships that might pose a conflict of interest be disclosed to potential research participants.[6,7] However, the effects of such disclosures are not well understood. Earlier empirical work[8,9] suggests little effect on willingness to participate, but methodological limitations make it difficult to know whether this finding applies to more realistic cases where a person is presented with a single financial disclosure and must make a decision about participating. Furthermore, recent qualitative work suggests that disclosure might affect outcomes other than willingness to participate and that the level of risk involved might influence these effects.[10,11]

In this study, we used a hypothetical clinical trial to examine the effects of financial interest disclosures on 5 main outcomes: (1) willingness to participate, which is important because clinical research is predicated on enrollment; (2) relative importance of financial disclosure because it is crucial to understand the context in which financial disclosures are used in patients' enrollment decision; (3) trust in research and researchers because disclosures might affect this factor that is associated with participation; (4) surprise about the financial relationship because it indicates how the disclosed information deviates from people's expectations; and (5) perceived quality of the research, as it is relevant to the perceived value of participation.

METHODS

We conducted an experiment in which we manipulated the type of financial disclosure each participant received as part of a description of a hypothetical clinical trial. Participants were a

convenience sample of adults in the United States with diabetes mellitus or asthma. Participants in each disease group were further categorized into 2 levels of disease severity.

Participants and Procedures

Participants were at least 18 years of age and were members of the Harris Interactive (Rochester, NY) Chronic Illness Panel or the Harris General Population Panel. These panels consist of adults in the United States who have agreed to be contacted about research opportunities. Harris sent recruitment e-mails in September 2005 and continued until at least 880 respondents were recruited for each of the 4 disease and severity categories (i.e., mild asthma, severe asthma, mild diabetes, severe diabetes). We used N=880 because this was the minimum number of respondents per group required to detect standardized effect sizes greater than 0.30 and 15-point differences with 80% statistical power. This recruitment strategy is akin to using electronically posted advertisements, which results in a convenience sample.

Respondents with asthma who had been hospitalized, visited an emergency department, or used an oral or injected steroid therapy in the past year for asthma were considered to have severe asthma. Respondents with diabetes mellitus who were using insulin or had visited an emergency department or been hospitalized for a diabetes-related event in the past year were considered to have severe diabetes. We excluded respondents with gestational diabetes and respondents with mild disease (either asthma or diabetes) who described their general health status as poor. The institutional review boards of the Duke University Health System, the Johns Hopkins Medical Institutions, and Wake Forest University determined that the study was exempt from the requirement for approval.

Clinical Trial Scenarios

Respondents in each group were presented with a written scenario (Appendix A, available online). Each scenario included a description of a hypothetical clinical trial evaluating a new oral medication pertinent to the respondent's disease, a description of the potential benefits and risks of participating in the clinical trial, and a disclosure statement revealing a financial interest in the research involving either the researcher or the institution in which the clinical trial was being conducted. The scenarios and disclosure statements were based on previous research and on input from an expert panel (Appendix B, available online).[10,12,13] In an effort to create both "low stakes" and "high stakes" situations, we manipulated the risks of participating in the hypothetical clinical trial to pose greater risks to respondents with more severe disease (i.e., damage to vital organs rather than headache, bloating, nausea, or rash). In contrast to previous research that presented the same respondents with multiple scenarios involving different financial relationships,[8] we selected a more realistic approach that provided each participant with only 1 depiction of a clinical trial that was related to his or her disease.

As part of the scenarios, each participant was randomly given 1 of 5 disclosure statements about a financial interest in the research. The disclosure statements included 1 describing a generic, nonspecific financial interest and 4 others giving specific descriptions of per capita payments, money received outside of the clinical trial (e.g., consulting fees), equity ownership by the researcher, and equity ownership by the institution (Table 1). All disclosure statements explained that an institutional review board and another committee had reviewed the financial interest, that these groups did not believe the interest would affect the safety or scientific quality of the clinical trial, and that more information was available upon request.

Measures

Before reading a scenario, respondents completed the Trust in Medical Research measure, a 4-item measure of trust in medical researchers. The scale was developed, piloted, and validated for this study.[14] After reading the scenario, respon-

Table 1. Disclosure Statements for the Hypothetical Clinical Trial Scenarios

	Disclosure
Generic disclosure	Dr Smith, the person leading this medical research study, might benefit financially from this study. [The Institutional Review Board (a committee that oversees research) and another committee at Welby Medical Center have reviewed the possibility of financial interest. They believe that the possible financial interest to Dr. Smith is not likely to affect your safety or the scientific quality of the study. If you would like more information, you may ask the medical researchers or the study coordinator.]*
Per capita payments	Dr Smith, the person leading this medical research study, might benefit financially from this study. Specifically, Acme Pharmaceuticals pays Dr Smith for study supplies, staff salaries, and for each person who agrees to participate in the study. This amount of money is just enough to cover the cost of running the study.*
Money outside of the study	Dr Smith, the person leading this medical research study, might benefit financially from this study. Specifically, this research study is supported by money from Acme Pharmaceuticals. In addition, Dr Smith receives extra money from Acme Pharmaceuticals for work that is not a part of this study. These activities may include consulting, advisory boards, giving speeches, or writing reports. Dr. Smith might receive hundreds or thousands of dollars for this work.*
Researcher owns equity	Dr Smith, the person leading this medical research study, might benefit financially from this study. Specifically, this research study is designed to test a product made by Acme Pharmaceuticals. Dr Smith has an investment in Acme Pharmaceuticals, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that Dr Smith could gain or lose money depending on the results of this study.*
Institution owns equity	Welby Medical Center, the institution conducting this medical research study, might benefit financially from this study. Specifically, this research study is designed to test a product made by Acme Pharmaceuticals. Welby Medical Center has an investment in Acme Pharmaceuticals, such as stock. The amount of money the investment is worth might be affected by the results of this study. This means that Welby Medical Center could gain or lose money depending on the results of this study.*

**The bracketed portion of the generic disclosure statement was repeated verbatim at the end of each of the other disclosure statements, except that the fifth disclosure (institutional equity) referred to the institution's rather than to Dr Smith's financial interest.*

dents answered questions developed specifically for this experiment regarding the respondent's likelihood of participating in the hypothetical clinical trial, the relative importance of the financial disclosure as compared to other aspects of the trial, change in trust in the researcher or institution, surprise at learning about the financial relationship, and the perceived effect of the financial interest on the scientific quality of the trial. These questions were developed based on results of a focus group study[10] and were subjected to 10 cognitive interviews to ensure the understandability and appropriateness of the response options.

Statistical Analysis

We compared respondents' characteristics and baseline trust in medical researchers among the 4 disease-severity groups using χ^2 tests for categorical variables and analysis of variance (ANOVA) for continuous variables. We calculated Pearson correlation coefficients to examine relationships among the 5 outcome measures (likelihood of participating in the trial, relative importance of the financial disclosure, change in trust, surprise regarding the financial interest, and the perceived effect of the financial interest on the quality of the trial).

We conducted factorial ANOVAs for all outcomes to examine the main and interactive effects of disease, disease severity, and disclosure type. When we found a main effect for disclosure type ($P<.05$), we examined all pairwise comparisons using independent-samples t tests. To examine relationships between each outcome and other respondent characteristics, we developed exploratory general linear models using backward-stepping variable selection. The variables considered in these models were sex, age, self-reported race/ethnicity, geographic region (East, Midwest, South, and West), education level, household income, work status, health status, and the "total trust" score from the Trust in Medical Research measure. Within these models, we also tested whether disclosure type interacted with respondent characteristics. We report these findings only when practically significant effects were present.

We report all effects from ANOVAs and other general linear models as standardized effect sizes (d) calculated as the difference in outcome between 2 groups divided by the SD of the outcome.[15] For the 5-point Likert scales, we computed d associated with a 2-point change in the scale. This study was designed to detect differences as small as $d=0.30$ with 80% statistical power. (A d of 0.30 is equivalent to a correlation of 0.15 and to the difference between the 50th and 38th percentiles of a distribution.) Because of the large number of statistical tests and the high statistical power of the study, we interpreted effects only if they were estimated precisely ($P<.05$) and $d\geq 0.30$. We assumed that statistically significant effects with smaller effect sizes were unlikely to have relevance for policy decisions. We also illustrated the effects on willingness to participate in the hypothetical clinical trial by dichotomizing the variable as "yes" ("I probably would participate" or "I definitely would participate") or "no/unsure" ("I definitely would not participate," "I probably would not participate," or "I am uncertain if I would or would not participate").

Many outcomes had skewed distributions, so we repeated all ANOVAs and general linear models using rank versions of the outcomes (i.e., Friedman nonparametric ANOVA). When results of the parametric and nonparametric tests disagreed, we report the parametric results only for effects that were significant in both the parametric and nonparametric models.

RESULTS

Table 2 shows characteristics of the respondents. Respondents were equally distributed across geographic regions of the United States, and the large majority was white. Overall, the respondents were well-educated and had middle to high household incomes. Baseline trust in medical researchers did not differ across groups.

Most respondents were either uncertain about participating (26%) or "probably" would participate (41%) in the hypothetical clinical trial. Although statistically significant effects were found for disease, disease severity, and the disease–severity interaction, the effects were small ($d\leq 0.20$; see Table 3). There was a significant main effect for disclosure type (see Table 4), with the largest difference ($d=0.29$) reflecting a greater willingness to participate in the trial when the researcher received per capita payments (mean 3.46, standard error [SE] 0.04) than when the researcher held an equity interest (mean 3.16, SE 0.04). When we dichotomized the variable for willingness to participate, a greater proportion of respondents would participate when the researcher received per capita payments (59%) compared to other types of financial interests (45% to 51%).

Although the respondents varied in the importance they attributed to the financial disclosure, most respondents felt that the disclosure was less important than other information about the hypothetical clinical trial (see Table 4), such as potential benefits and risks and the purpose of the research. The relative importance of the disclosure depended on the type of disclosure; the largest difference ($d=-0.34$) indicated that the disclosure was more important for studies in which the researcher owned equity (mean −0.89, SE 0.03) than for studies in which the researcher received per capita payments (mean −1.20, SE 0.03). We observed no practically significant effects for disease or disease severity.

Most of the respondents (59%) felt that the possibility of financial benefit did not change their trust in the researcher or institution. Thirty-six percent of the respondents indicated, however, that their trust had diminished as a result of the disclosure. Changes in trust varied depending on the disclosure. A disclosure that the researcher received per capita payments was least likely to change respondents' level of trust (mean 3.15, SE 0.03), whereas a disclosure that the researcher held an equity interest was most likely to reduce trust (mean 3.51, SE 0.03, $d=0.52$). Change in trust was not related to disease or disease severity.

The majority of respondents (67%) was "not at all surprised" that the researcher or institution might benefit financially from the hypothetical clinical trial. The extent of surprise varied by disclosure type. Respondents were least surprised to learn that the researcher received per capita payments (mean 1.34, SE 0.03) and were most surprised to learn that the researcher owned equity (mean 1.74, SE 0.03, $d=-0.45$). Although there was a statistical interaction between disclosure type and disease severity ($P=.03$), this effect was very small (see Table 3). In exploratory multivariable modeling, nonwhite respondents were more surprised than white respondents about generic disclosures ($d=0.41$), but we found no consistent differences by race/ethnicity for other disclosures.

Table 2. Respondent Characteristics by Disease and Disease Severity*

Characteristic	Disease and Disease Severity			
	Asthma		Diabetes	
	Not severe (*n*=912)	Severe (*n*=900)	Not Severe (*n*=908)	Severe (*n*=903)
Female sex	582 (63.8)	620 (68.9)	463 (51)	502 (55.6)
Age, mean±SD, year	43.3± 13.6	45.8± 12.5	53.7± 11.5	49.3± 13.4
Race/ethnicity				
American Indian/ Alaska Native	9 (1.0)	9 (1.0)	10 (1.1)	9 (1.0)
Asian/Pacific Islander	15 (1.6)	7 (0.8)	11 (1.2)	6 (0.7)
Black	18 (2.0)	22 (2.4)	21 (2.3)	17 (1.9)
Hispanic	11 (1.2)	26 (2.9)	11 (1.2)	13 (1.4)
White	799 (87.6)	788 (87.6)	824 (90.7)	822 (91.0)
Multiracial	22 (2.4)	21 (2.3)	7 (0.8)	16 (1.8)
Other	8 (0.9)	7 (0.8)	5 (0.6)	4 (0.4)
Geographic region				
East	217 (23.8)	231 (25.7)	179 (19.7)	176 (19.5)
Midwest	198 (21.7)	210 (23.3)	220 (24.2)	229 (25.4)
South	263 (28.8)	275 (30.6)	339 (37.3)	318 (35.2)
West	234 (25.7)	184 (20.4)	170 (18.7)	180 (19.9)
Education level				
High school or less	87 (9.5)	127 (14.1)	139 (15.3)	138 (15.3)
Some college	349 (38.3)	426 (47.3)	411 (45.3)	391 (43.3)
Bachelor's degree	223 (24.5)	167 (18.6)	157 (17.3)	179 (19.8)
Graduate school	253 (27.7)	180 (20.0)	201 (22.1)	195 (21.6)
Annual income				
<$15,000	43 (4.7)	89 (9.9)	52 (5.7)	90 (10.0)
$15,000 to $24,999	97 (10.6)	85 (9.4)	79 (8.7)	108 (12.0)
$25,000 to $34,999	102 (11.2)	106 (11.8)	98 (10.8)	116 (12.8)
$35,000 to $49,999	150 (16.4)	158 (17.6)	156 (17.2)	150 (16.6)
$50,000 to $74,999	189 (20.7)	192 (21.3)	198 (21.8)	150 (16.6)
$75,000 to $99,999	104 (11.4)	91 (10.1)	113 (12.4)	80 (8.9)
$100,000 to $124,999	61 (6.7)	59 (6.6)	60 (6.6)	45 (5.0)
≥$125,000	52 (5.7)	40 (4.4)	50 (5.5)	59 (6.5)
Employment status				
Full-time	501 (54.9)	422 (46.9)	422 (46.5)	371 (41.1)
Part-time or self-employed	175 (19.2)	145 (16.1)	135 (14.9)	128 (14.2)
Other†	236 (25.9)	333 (37.0)	351 (38.7)	404 (44.7)
Health status (1=poor, 5=excellent), median (interquartile range)	3 (3–4)	3 (2–3)	3 (2–3)	2 (2–3)
Medical conditions				
Asthma	912 (100.0)	900 (100.0)	122 (13.4)	105 (11.6)
Diabetes	13 (1.4)	135 (15.0)	908 (100.0)	903 (100.0)
High blood pressure	185 (20.3)	300 (33.3)	491 (54.1)	451 (49.9)
Kidney disease	5 (0.6)	27 (3.0)	9 (1.0)	62 (6.9)
Arthritis	220 (24.1)	346 (38.4)	272 (30.0)	285 (31.6)
Trust in medical researchers, mean±SD	12.3±2.7	12.5±2.7	12.4±2.8	12.4±2.7

(*continued on next page*)

Values are expressed as number (percentage) unless otherwise indicated. All results from analyses of variance and χ^2 tests were significant at $P<.05$, except for the "trust in medical researchers" variable

†*Includes homemaker, student, retired, and unemployed*

Regardless of disease, disease severity, and disclosure type, all mean ratings reflected a perception that the financial interest decreased the quality of the science. Disclosure type was the only factor generating differences that approached the $d \geq 0.30$ criterion. The largest difference (d=0.28) was between the disclosures of per capita payments and ownership of equity. Respondents who received the disclosure regarding per capita payments (mean 2.95, SE 0.03) perceived less of a reduction in scientific quality than those receiving the disclosure regarding a researcher owning equity (mean 2.70, SE 0.03). Although there was a statistical interaction between disclosure type and disease severity (P=.03), this effect was very small (see Table 3).

Correlations among the five outcome variables are shown in the electronic supplementary material.

DISCUSSION

Current policies and practices regarding the disclosure of financial interests in clinical research are in a state of flux and uncertainty. Our findings help to ground discussions about financial disclosures by identifying their likely effects. Several important points arise from the findings. First, contrary to concerns that potential research participants might be unable to grasp the nature and implications of financial interests in research,[16] we found that respondents were sensitive to some of the financial interests disclosed. Respondents consistently viewed a researcher owning equity less favorably than a researcher receiving per capita payments. Respondents appeared to view other types of financial interest

Table 3. Effects of Disease, Disease Severity, and Disclosure Type on Study Outcomes

Outcome Measure	Mean (SE)	*P*	Effect Size*
Likelihood of participation			
Asthma		.91	0.01
Mild asthma	3.23 (0.03)		
Severe asthma	3.23 (0.04)		
Diabetes mellitus		<.001	0.20
Mild diabetes mellitus	3.43 (0.03)		
Severe diabetes mellitus	3.22 (0.03)		
Type of financial disclosure†		<.001	
Generic	3.28 (0.04)		
Per capita payments	3.46 (0.04)		
Money outside of the study	3.22 (0.04)		
Researcher owns equity	3.16 (0.04)		
Institution owns equity	3.28 (0.04)		
Relative importance of disclosure			
Asthma		.13	0.07
Mild asthma	−0.96 (0.03)		
Severe asthma	−1.02 (0.03)		
Diabetes mellitus		.19	0.06
Mild diabetes mellitus	−1.10 (0.03)		
Severe diabetes mellitus	−1.04 (0.03)		
Type of financial disclosure†		<.001	
Generic	−1.05 (0.03)		
Per capita payments	−1.20 (0.03)		
Money outside of the study	−1.00 (0.03)		
Researcher owns equity	−0.89 (0.03)		
Institution owns equity	−1.02 (0.03)		
Change in level of trust			
Asthma		<.001	0.22
Mild asthma	3.48 (0.02)		
Severe asthma	3.33 (0.02)		
Diabetes mellitus		.91	0.01
Mild diabetes mellitus	3.32 (0.02)		
Severe diabetes mellitus	3.33 (0.02)		
Type of financial disclosure†		<.001	
Generic	3.35 (0.03)		
Per capita payments	3.15 (0.03)		
Money outside of the study	3.43 (0.03)		
Researcher owns equity	3.51 (0.03)		
Institution owns equity	3.39 (0.03)		
Surprise about financial interest			
Asthma		.40	0.04
Mild asthma	1.58 (0.03)		
Severe asthma	1.55 (0.03)		
Diabetes mellitus		.01	−0.12
Mild diabetes mellitus	1.44 (0.03)		
Severe diabetes mellitus	1.54 (0.03)		
Type of financial disclosure†			
Generic disclosure		.007	−0.20
Mild disease	1.39 (0.05)		
Severe disease	1.57 (0.05)		
Per capita payments		.44	−0.06
Mild disease	1.31 (0.05)		
Severe disease	1.37 (0.05)		
Money outside of the study		.24	−0.09
Mild disease	1.48 (0.05)		
Severe disease	1.56 (0.05)		
Researcher owns equity		.60	0.04
Mild disease	1.76 (0.05)		
Severe disease	1.72 (0.05)		
Institution owns equity		.13	0.11
Mild disease	1.61 (0.05)		
Severe disease	1.51 (0.05)		
Perceived effect on scientific quality			
Asthma		<.001	−0.28
Mild asthma	2.66 (0.03)		
Severe asthma	2.91 (0.03)		
Diabetes mellitus		.78	−0.01
Mild diabetes mellitus	2.80 (0.03)		
Severe diabetes mellitus	2.81 (0.03)		
Type of financial disclosure†			
Generic disclosure		.58	−0.04
Mild disease	2.76 (0.05)		
Severe disease	2.80 (0.05)		
Per capita payments		.03	−0.16
Mild disease	2.88 (0.05)		
Severe disease	3.02 (0.05)		
Money outside of the study		.86	−0.01
Mild disease	2.75 (0.05)		
Severe disease	2.76 (0.05)		
Researcher owns equity		.001	−0.24
Mild disease	2.60 (0.05)		
Severe disease	2.81 (0.05)		
Institution owns equity		<.001	−0.29
Mild disease	2.66 (0.05)		
Severe disease	2.91 (0.05)		

**Standardized effect size equals the difference between means divided by the standard deviation*
†See Table 4 for pairwise comparisons among disclosure types

as falling somewhere between the 2 extremes. This finding suggests that some potential research participants can differentiate among types of financial interests. Also, policy makers should consider the relative sense of unease we observed about researchers owning equity as they determine what types of financial interests to permit in clinical research.

Second, disclosures of other financial interests did not substantially affect respondents' willingness to participate in the hypothetical clinical trial. In general, respondents were very willing to participate (45% to 59%). Consistent with this finding, most respondents assigned far less importance to information regarding financial interests than to other information about the trial. The findings regarding respondents' unease about researchers owning equity and the lack of an effect on willingness to participate corroborate data reported by Kim et al.[8] and Hampson et al.[9]

In contrast to our findings regarding willingness to participate, trust in medical researchers and institutions was substantially affected by the type of financial interest disclosed. The disclosures made over one third of respondents less trusting of researchers and institutions, although they led to greater trust for some respondents. Greater trust might result from viewing disclosure as an indication of a researcher's honesty.[10,17] Differences in trust among the types of disclosures occurred regardless of the respondent's level of trust before reading the information about the hypothetical clinical trial. Changes in trust appeared to be related to variations in willingness to participate and in respondents' perceptions that financial interests lowered the scientific quality of the hypothetical trial. However, the small size of these relationships suggests that they are separate variables. The findings regarding trust are important, given how central trust can be to participation in research and to public acceptance of research findings,[18] and considering the need to ensure that the clinical research enterprise merits the trust that participants confer on it.

Recent widespread attention to financial interests in clinical research may help to explain why many respondents were not surprised by such interests in the scenarios. However, some respondents were surprised, especially those who learned that

Table 4. Differences in Study Outcomes by Type of Financial Disclosure*

Outcome	Generic Disclosure	Per Capita Payments	Money Outside of the Study	Researcher Owns Equity
Likelihood of participating				
Generic disclosure	–			
Per capita payments	−0.17 (.002)	–		
Money outside of the study	0.06 (.23)	0.23 (<.001)	–	
Researcher owns equity	0.12 (.02)	0.29 (<.001)	0.06 (.27)	–
Institution owns equity	0.00 (>.99)	0.17 (.002)	−0.06 (.22)	−0.12 (.02)
Relative importance of disclosure				
Generic disclosure	–			
Per capita payments	0.17 (.001)	–		
Money outside of the study	−0.05 (.36)	−0.22 (<.001)	–	
Researcher owns equity	−0.17 (.001)	**−0.34** (<.001)	−0.13 (.02)	–
Institution owns equity	−0.03 (.56)	−0.20 (<.001)	0.02 (.73)	0.14 (.006)
Change in level of trust				
Generic disclosure	–			
Per capita payments	0.28 (<.001)	–		
Money outside of the study	−0.11 (.03)	**−0.40** (<.001)	–	
Researcher owns equity	−0.24 (<.001)	**−0.52** (<.001)	−0.12 (.02)	–
Institution owns equity	−0.05 (.31)	**−0.34** (<.001)	0.06 (.24)	0.18 (<.001)
Surprise about financial benefit				
Generic disclosure	–			
Per capita payments	0.16 (.003)	–		
Money outside of the study	−0.04 (.44)	−0.20 (<.001)	–	
Researcher owns equity	−0.29 (<.001)	**−0.45** (<.001)	−0.25 (<.001)	–
Institution owns equity	−0.09 (.09)	−0.25 (<.001)	−0.05 (.36)	0.20 (<.001)
Perceived effect on scientific quality				
Generic disclosure	–			
Per capita payments	−0.20 (<.001)	–		
Money outside of the study	0.03 (.63)	0.22 (<.001)	–	
Researcher owns equity	0.09 (.09)	0.28 (<.001)	0.06 (.23)	–
Institution owns equity	−0.01 (.87)	0.19 (<.001)	−0.03 (.52)	−0.10 (.07)

**For all outcomes, overall effect of disclosure type was significant (P<.05). Values are standardized effect sizes calculated as (mean$_c$ − mean$_r$)/SD. Values in parentheses are P values from independent-samples t tests. Effect sizes≥0.30 are shown in boldface*

the researcher held an equity interest in the research, suggesting that it would be inappropriate not to disclose such information when recruiting research participants. Surprise following enrollment could result in disappointment, anger, or noncompliance among participants. Moreover, this finding raises challenging questions about what types of disclosures are appropriate to help ensure that research participants are adequately informed before enrollment.

The main findings did not differ by disease or disease severity. We selected participants with 1 of 2 specific diseases to make the scenarios more salient and realistic, and we posed risks that were greater for those with greater disease severity to test the potential effects of disclosures in different research contexts. The consistency of the findings across the 4 disease-severity categories suggests that the findings may be generalizable to other clinical and research scenarios.

The survey has several limitations. It asked respondents about their willingness to participate in hypothetical clinical trials relevant to their conditions rather than in actual clinical trials. Further research is necessary to confirm the findings in the context of actual clinical research. In addition, the experiment was conducted using a specialized convenience sample of self-selected Internet users. One challenge in research on clinical research itself is that there is no registry of all trial participants in the United States, making it difficult to assess the generalizability of any research findings to the target population. Compared to adults who identified themselves as clinical trial participants in a large, nationally representative sample in the United States,[19] our sample had a similar distribution of race/ethnicity. However, our sample had relatively fewer adults older than 60 years. In addition, although the proportion of college graduates was similar, our sample had a relatively higher proportion of participants with some college education (as opposed to a high school education). Thus, while the relative differences (or lack of differences) among the disclosure types might generalize to broader populations, it is unclear how well the absolute levels of the outcome variables can generalize. Finally, it is likely that the quantitative measures of patient reactions used in this study do not reflect the richness and subtlety of patients' full experiences.

In conclusion, we found in this study, with the exception of researcher owning equity, disclosure of most financial interests in research, as recommended in recent policy statements,[7,20] is unlikely to affect the willingness of potential research subjects to participate in research. This conclusion appears to hold for patients with both lesser and greater disease severity. Furthermore, patients viewed financial interests as less important than other information about the study. Future efforts should be directed at determining how best to disclose acceptable financial interests so as to achieve adequate understanding while not unduly burdening the research enterprise. This does not preclude efforts to identify and eliminate unacceptable financial relationships in clinical research. In addition, given that disclosures can affect participants' trust, it will be important to monitor potential negative effects on trust over time.

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Corresponding Author: *Kevin P. Weinfurt, PhD; Center for Clinical and Genetic Economics, Duke Clinical Research Institute, Duke University School of Medicine, P.O. Box 17969, Durham, NC 27715, USA (e-mail: kevin.weinfurt@duke.edu).*

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