FINANCIAL CONFLICTS OF INTEREST

AND THEIR REGULATION:

THE PERSPECTIVES OF RESEARCH PARTICIPANTS

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ABSTRACT

OBJECTIVE: There is substantial controversy about researcher and institutional financial conflicts of interest in clinical trials and what safeguards should be implemented. We undertook a survey of cancer clinical trial participants to determine their attitudes and preferences regarding financial ties between researchers, medical centers, and companies whose drugs are being tested and potential safeguards.

METHODS: A survey on financial conflicts of interest and potential safeguards was developed and subjected to cognitive and behavioral pre-testing. Trained interviewers, unaffiliated with the underlying cancer trials, conducted in-person interviews with 253 individuals (93% response rate) participating in cancer research trials at 5 geographically diverse medical centers in the U.S.

RESULTS: The vast majority of participants expressed little to no worry about researchers' (91%) or institutions' (90%) financial ties to drug companies. A large majority of respondents (82%) reported that if the researcher received honoraria for speaking from the company that makes the drug in the trial they would still participate, while 75% would still participate if the researcher received consulting fees, owned stock (76%), or received royalty payments (70%). Similarly, 77% reported they would enroll even if their cancer center had stock in the company whose drug was being evaluated in their study or received royalty payments on their patent (79%). Indeed, most participants found researcher honoraria (81%) and consulting for the company whose drug is being tested (82%) to be ethically acceptable. Over half of participants would permit researchers and institutions to hold stock in companies

whose drug they are testing. Overall, 40% of participants wanted disclosure of the oversight system for researchers, 31% disclosure of actual financial interests, while 17% thought no disclosure to participants was necessary. Similarly, 43% of participants wanted disclosure of oversight system for institutional financial interests, 33% disclosure of actual financial interests, while 16% thought disclosure of institution financial ties was unnecessary. Respondents with greater education were significantly more likely to worry about financial ties and to advocate prohibiting cancer centers from owning stock in companies whose drugs were being tested at the institution.

CONCLUSIONS: Most cancer patients participating in clinical trials 1) were not worried about financial ties between researchers, medical centers, and drug companies whose drugs were being tested, 2) reported that they would have enrolled in the trial even if they had known about such financial ties, and 3) found these financial ties ethically acceptable. Research participants preferred to know there was an oversight system in place to protect against conflicts of interest rather than to have the detailed financial ties of researchers or the institution disclosed to them.

There are two major reasons to be concerned about financial conflicts of interest (COI) in the clinical research: they might increase risks to participants or undermine the scientific integrity of the research. To address financial COIs, many commentators and organizations have called for disclosure of financial interests to potential research participants. For instance, the most recent version of the Declaration of Helsinki mandates that "each potential subject must be adequately informed of … any possible conflicts of interest."[1] The American Medical Association, the U.S. Department of Health and Human Services, the Association of American Universities, and the Association of American Medical Colleges have also recommended disclosure of COIs to potential research subjects.[2-5] A 2004 survey found that nearly half of academic medical centers had policies concerning disclosure of COI information to prospective research participants, with substantial variation in the type and amount of information required.[6]

Advocates of disclosure argue that it allows participants to assess whether the financial interests might pose increased risks or otherwise influence their willingness to enroll. Disclosure to participants may also maintain public trust and transparency in the research enterprise, and may discourage financial ties among researchers and institutions.[6-10] However, some ethicists and physicians have criticized disclosure to research participants.[8,10,12-15] Rather than placing the onus of accountability on researchers and institutions, it passes responsibility to the group with the least power and fewest options.[10,16] Others argue that research participants may not be well-positioned to interpret the disclosed information and assess how it might affect their own interests.[8,10,11] Disclosure of inconsequential financial relationships may unnecessarily disrupt the researcher-participant

relationship.[10] Finally, disclosure to participants certainly cannot ensure scientific integrity of the research enterprise.

Little is known about the views of the very group supposed to be protected—research participants—regarding potential COIs, their disclosure, or other safeguards. The only two studies that assessed attitudes on COIs have serious limitations.[17,18] One 1995 study interviewed patients of physicians who participate in post-marketing Phase IV studies, and the other used the Internet to survey people who claimed they might be willing to be research participants in the future.[17,18] Neither group was asked about institutional COIs. Furthermore, respondents did not likely appreciate the burdens of understanding the information, applying it in the decision making process, and the limited range of treatment and/or research options provided to them. Finally, both studies had low response rates.[17,18]

To elucidate research participants' views about COIs, disclosure, and other safeguards, and to address the limitations of prior studies, we interviewed participants in cancer clinical trials. We selected these individuals because cancer trials represent a substantial fraction of all clinical research and tend to have substantial industry involvement.[19] Most important, cancer patients face a serious and often life threatening disease, making them extremely vulnerable to any adverse effects of financial COIs.

METHODS

Study Participants

Between November 2004 and 2005, individuals enrolling or enrolled in cancer clinical trials were identified at 5 geographically dispersed cancer centers: the National Cancer Institute (Bethesda, MD), the Dana-Farber Cancer Institute (Boston, MA), the Fred Hutchinson Cancer

Research Center (Seattle, WA), the University of Colorado Cancer Center (Denver, CO), and the Yale Cancer Center (New Haven, CT). Individuals were eligible if they 1) had previously consented to participate in a cancer research study, 2) were at any cycle in that study, 3) were over the age of 18, and 4) understood written and spoken English. A total of 272 cancer research participants were approached and 253 agreed to participate (response rate= 93%).

Survey Development

The survey was designed by NIH investigators and survey methodologists from the Research Triangle Institute (RTI) using a 5 step process. A literature search identified concerns about COI, proposals for what information should be disclosed to research participants, and other safeguards. Second, questions from a previous survey were examined.[18] Third, questions were developed about 4 potential researcher COIs: 1) stock ownership, 2) honoraria for lectures, 3) payment for consulting, and 4) royalty payments for patents and 3 potential institutional COIs: 1) stock ownership, 2) per capita payment for individuals enrolled in research, and 3) royalty payments for patents. In addition, questions on proposed safeguards for both researcher and institutional COIs were also were developed. Questions were adapted from the Wake Forest University Trust Scales,[19] the Wisconsin Brief pain inventory,[20] and the Medical Outcomes Survey 36-Item Short-Form Health Survey.[21] Eastern Cooperative Oncology Group (ECOG) performance status was also assessed.[22] A draft survey instrument was subjected to two rounds of cognitive interviews with patients to ensure comprehensibility. After revision, the survey instrument was subjected to behavioral testing to ensure the wording of the questions and response categories were clear and easily spoken.

The final instrument contained 45 questions in six domains: 1) awareness of and concern about COI and their regulation, 2) impact of financial COI on study participation, 3) attitudes about policies and practices regarding COI in research, 4) attitudes about disclosure of COIs in research, 5) respondents' trust in their physician, researcher, and institution, and 6) respondents socio-demographic and medical characteristics.

Because the phrase "conflict of interest" has negative valence, questions instead used the descriptive and non-judgmental term "financial ties", such as "Do you think the oversight system for regulating the financial ties of (this cancer center) and its researchers…." Similarly, descriptive phrases were used to convey types of financial ties. For instance, instead of "consulting," the phrase "received payment from the drug company for offering advice about their area of expertise" were used. Wording of some questions were: "Imagine that you learned that **your doctor** at (cancer center) had financial ties with the company that makes the drugs used in your study….Please tell me whether it would have influenced your decision to participant in your cancer study. It would have influence you **to** participate, influenced you **not** to participate, made no difference?" (Emphasis in original) "Now I will read you a list of financial ties that **your doctor** at (cancer center) could have with the drug company related to your study. Please tell me which ones, if any, you think you doctor should be **permitted to have**?" (Emphasis in original). Participants were told to identify their "doctor" for the purposes of the survey as "the doctor who you see most often when you come to (cancer center)."

Survey Administration

The survey was administered in-person by nurses and health care professional interviewers unaffiliated with the underlying cancer research trials who were trained in non-directive interviewing by RTI. The research participants were already attending the medical center for an appointment, usually for research related tests or treatments. The mean duration of the survey was 30 minutes (median 29 minutes).

Human Subjects Protections

The IRBs at all five participating cancer centers approved the protocol, consent document, and survey instrument. All participants gave written informed consent.

Data and Statistical Analysis

The survey results are summarized and presented using percent of responses. Differences between responses for subgroups defined by patient characteristics are tested by either the Fisher's exact test or the Kruskal-Wallis test. Odds ratios are estimated and their 95% confidence intervals calculated.

RESULTS

Respondents' Characteristics

Of 253 respondents, 56% were male and 92% were white. Approximately a quarter were under 50 years of age, 59% were between 50 and 69 years of age, and 16% were over 70 (Table 1). The respondents were well insured, well educated, and well-off, with 96% having health insurance, 53% having a college degree or more education, and 44% with annual incomes over $75,000 (Table 1).

Respondents had a variety of cancers; no single diagnosis accounted for more than 13% of respondents (Table 1). On average, respondents had their cancer for 4 years (median 2 years). Prior to enrolling in their cancer study, 35% had **not** previously received any chemo- bio- or radiotherapy treatments, 30% had received 1 or 2 prior regimens, and 35% had received 3 or more regimens (Table 1). Overall, 16% were just starting the trial, 23% had received 1 cycle of the experimental intervention, 20% had received 2 or 3 cycles, and the remaining 41% had received 4 or more cycles.

About half had moderately or seriously considered treatment options other than their current research trial, while 35% had not considered any other option, 10% had slightly considered other options.

Respondents were active with few symptoms. Overall, 57% had normal physical activity (ECOG 0), 30% had minor limitations in activity (ECOG 1), and 13% were in bed less than half of the day (ECOG 2). About a quarter had a moderate or great deal of pain, and only 5% had depression or serious psychological distress.

Over 96% of respondents agreed or strongly agreed that they had complete trust in their doctor and in the cancer center.

Concerns about Financial Ties and Conflicts of Interest

Despite extensive press coverage of conflicts of interest during the interview period, only 7% of respondents had heard or read "**a lot** about financial ties related to clinical research studies," 16% had heard or read a **moderate** amount, while fully 77% had heard or read **little or nothing**. Only 2 (<1%) were **very** worried that the doctor running their clinical research study has "financial ties with the company that makes the drug used in the study," 6% were

somewhat worried, 11% **a little** worried, and 80% were **not worried at all** (Table 2). Of respondents who were not worried, 48% acknowledged they had not thought about such financial ties, while 36% were confident their doctor and/or medical care would not be influenced by such financial ties. Similarly, respondents were not particularly worried about financial ties between their cancer center and "the company that makes the drug used in the study." Only 2 (<1%) people were **very** worried,7% were **somewhat** worried, 21% a **little** worried, and 70% were **not at all** worried (Table 2). Again, 49% had not thought about financial ties between the cancer center and drug companies, 23% thought such ties would not affect their medical care, and 19% reported having trust in the oversight system in place.

Financial Interests and Research Participation

For a large majority of these cancer patients, financial ties of researchers and cancer centers would have made no difference to their decision to participate in the cancer clinical trial (Table 3). Of respondents, 82% would still participate if the researcher received honoraria for speaking from the company that makes the drug in the trial, while over 70% would still participate if the researcher received consulting fees, owned stock, or received royalty payments (Table 3). Similarly, 77% would enroll even if their cancer center had stock in the company whose drug was being evaluated in their study, 79% would still enroll if the institution received royalty payments on a patent, and 83% would participate even if the institution received a per capita payment for enrolling patients (Table 3). Less than 15% of respondents reported that knowledge of a financial tie would have stopped their participating in the cancer trial (Table 3).

The reasons given by respondents for the limited impact of financial interests on their decision to participation varied. For 40% of cancer patients, they would still participate despite financial ties because they believe they had no alternative or this was the way to get the best oncologist. Another 21% were sure the cancer center was overseeing the financial ties, and 14% believed the financial interest would not influence their care.

Most of the respondents felt that it was acceptable for their research doctor or cancer center to have a financial relationship with companies whose drug is involved in the research. Overall, 64% of participants thought it acceptable for researchers to own stock in the company whose drug is being evaluated in the trial, 82% thought it acceptable for researchers to consult to the company, 81% to receive a speaking honoraria from the company, and 70% felt the researcher could receive royalty payments on patents (Table 4). Similarly, 57% thought it acceptable for the cancer center where their research trial was being conducted to "own stock in the drug company whose drug is being used in the trial", while 72% found it acceptable for the cancer center to accept royalty payments for a patent, and 78% to receive per capita payments for enrollment in these trials.

Safeguards Protecting Against Conflicts of Interest

Overall, 62% of respondents believed there was an oversight system in place to monitor financial ties between researchers, cancer centers, and the companies whose agent was being tested. However, when asked, most could not specify a system but suggested "a body overseeing studies" must be monitoring the financial ties, or that there "must be a process during study implementation" such as an "independent oversight committee to screen MD's

credentials and relationship with drug companies." In addition, one-third stated that they did not know if there was such an oversight system.

When asked about disclosure of financial ties, 31% of respondents thought researchers should be required to tell study participants about the financial ties regardless of the amount of money involved (Table 5). Conversely, 40% thought researchers should tell participants about the oversight system, another 26% thought researchers either should **not** be required to disclose to research participants or only if the financial ties exceed a certain monetary level. Similarly, 33% thought research participants should be told about financial ties between cancer centers and companies whose drug is being tested regardless of the value. Conversely, 43% of respondents thought research participants should be told about the oversight system in place rather than the cancer center's specific financial ties to drug companies. Another 22% believed research participants should not be told about financial ties or only if they exceed a specified amount.

At the end of the survey, only 1 participant (<1%) was **very** worried about financial ties between doctors or cancer centers and the drug company related to the cancer study, 5% were **somewhat** worried, and over 90% were a **little** or **not worried at all**.

Predictors of Attitudes and Preferences

There was no consistent association between age, sex, race, religion, income, type of cancer, phase of study, or current cancer center and worry about financial interests, willingness to enroll in research studies with conflicts of interest, or views of what were appropriate financial ties. The only factor that consistently predicted respondents' attitudes was educational level. Respondents with higher education were significantly more worried about

the cancer center's financial interests with companies whose drugs were under evaluation (12% worried among those with high school level education, 27% among those with some college or a college graduate and 47% among those with post-graduate training, $p<0.001$). A similar trend was found concerning researchers' financial ties to drug companies (8% of participants with a high school education were worried, 17% of participants with some college or a college graduate and 31% of those with post-graduate training, $p=0.001$). Finally, those with more education were significantly less likely to permit cancer centers to own stock in companies whose drugs were being researched at the institution (67% of respondents with high school education, 65% of those with some college or college degree, while only 44% of those with post graduate training would permit such institutional financial interests, $p=0.008$). Importantly, there was no significant association between having higher education level and being more likely to report having heard or read about financial conflicts of interest.

DISCUSSION

In this study, most clinical research participants at 5 cancer centers had few concerns about financial ties between their physician-researcher or their cancer center and companies whose drug was being tested. A large majority of research participants did not view such financial ties as inappropriate, would not have changed their decision to participate in the research study even if the financial ties were disclosed, and were confident about the existence of an oversight system.

Despite substantial media coverage of financial conflicts of interest during the survey period, including at the very institutions at which the survey was conducted, more than 75% of respondents had not heard or read about such financial ties. Further, the vast majority were

not concerned about these financial ties at all. This is not because these research participants are naïve, unsophisticated, or uneducated. In fact, they represent the socio-economically privileged members of American society who should be the most sophisticated group regarding financial interests. Only among respondents with post-graduate degrees did a majority worry about or want to prohibit these financial ties.

These data suggest that at least among participants in cancer trials, financial links between researchers, cancer centers and drug companies are neither salient nor worrisome nor notable. Why not? For these cancer patients concerns about health and getting what they consider the best doctor or experimental treatment seem to predominate. This seems to be confirmed by the findings that over 70% of respondents would still enroll in their research trial even if they knew about financial ties between researchers, cancer centers, and companies whose drug is being tested. In addition, it is probably psychologically essential for these research participants to trust that their doctors and cancer centers would not let anything, including financial ties, compromise their medical interests.

Unlike the two prior surveys involving either general medical patients or people who said they might be willing to participate in research but were not actual research participants, these data reflect the views of trial participants. Substantiation of these findings come from unpublished results of focus groups conducted by senior NIH officials in which research participants and patient advocates—including many from the non-cancer community—indicated they were minimally concerned about researchers' financial conflicts of interest; they were more concerned about making progress in curing major diseases, and thought collaboration between academic researchers and pharmaceutical companies was necessary for making progress (personal communication, Thomas R. Insel, M.D., Director, NIMH

regarding the National Institute of Mental Health meeting for Research Progress held on June 19, 2004).

This study suggests that disclosure of financial ties to research participants with serious and life threatening diseases may not serve as a meaningful bulwark against the potential problems of conflicts of interest. Almost half of respondents did not seriously consider any other treatment options besides their current research trial and over 70% thought disclosure of financial ties would not change their research participation. It may be that these individuals' desire to receive what they view as their best treatment option in a life-threatening situation outweighs worries about any financial ties. Indeed, while 20 to 30% of the research participants thought various financial ties should be prohibited, for fewer than 15% of them might disclosure have induced them **not** to participate in the research trial. This discrepancy merits additional exploration. But, at least for vulnerable patients, such a discrepancy emphasizes that disclosure is unlikely to protect against the potential harms of financial interests even when patients want them prohibited.

Surprisingly, most respondents thought that the common financial ties between researchers, cancer centers, and drug companies should be permitted. Importantly, they also distinguished among types of financial ties. Respondents were more inclined to permit researchers' consulting than stock ownership and per capita payments to institutions than stock holding by institutions. These findings suggest participants think not all financial ties should be regulated in the same manner. The reasons for these views are unclear. These research participants may recognize that many of the recent cancer breakthroughs have been drugs developed by the pharmaceutical and biotechnology industries and tested at academic medical centers. Hence, some may feel that some types of ties, such as consulting or per

patient payments, are necessary to facilitate the conduct of research and to make progress against cancer.[23]

There was wide variation in participants' view about what should be disclosed and to whom. How to handle the minority of research participants who would want disclosure of all financial interests when the majority would not want such disclosure is challenging. This is particularly vexing because, as some ethicists argue, providing financial interest information may not be neutral to all participants. Some might argue that financial ties are important and that if 30% of the participants believe disclosure is important then it should be included in consent documents. This is especially true since those who prefer not to have the information can ignore it. Others might argue that because disclosure is time consuming and potentially confusing and worrisome, and of little concern to the majority of research participants, mandatory inclusion of detailed financial information on all consent documents is inappropriate or burdensome.

These data suggest a very important policy recommendation: The focus of safeguards should not be on disclosure of specific financial ties to research participants, but on developing oversight committees to monitor, manage, and, if necessary, prohibit potential conflicts of interest. Among these participants in cancer trials, there was little enthusiasm to receive disclosure of financial ties; one third or less thought mandatory disclosure of all financial ties to research participants was most important. Furthermore, disclosure to participants fails to address the threat posed by conflicts of interest to the integrity of the scientific enterprise through compromising research design, interpretation and dissemination of data. Hence, oversight, monitoring, management, and, if appropriate, prohibition by a monitoring board may be the best strategies to protect against conflicts of interest. This

approach protects scientific integrity and accords with the concerns of research participants. Indeed, the majority of research participants believed these oversight boards and safeguards are already in place for monitoring financial ties, even if they could not specify what they were. If such boards are to protect against both researcher **and** institutional financial conflicts of interest it may be necessary to constitute oversight bodies with external, unaffiliated members to oversee institutional financial interests.[24]

This study has several limitations. First it only involved individuals with cancer participating in cancer research. The data might not generalize to healthy volunteers or research participants with illnesses other than cancer. Also, these data might not generalize to individuals who are considering but have not yet enrolled in research, or those who are less inclined to enter trials than the sample included in this study. The participants in this study tended to be well-educated, well-off, older, and Caucasian. Their views may not be generalizable to other populations such as minorities and the less educated. However, the participants in this study reflect the demographic characteristics of the larger cancer research participant pool.[25] Furthermore, the trends suggest that more educated people are less tolerant of financial conflicts of interest, suggesting a bias toward over- rather than underestimate of participants' concerns.

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Table 1: Characteristics of Study Participants

		Number	Percent°
Sex	Male	141	56%
	Female	112	44%
Age	< 50	61	24%
	50-59	82	33%
	60-69	66	26%
	≥70	41	16%
Race	White	233	92%
	Non-white	20	8%
Education	High School Graduate or less	53	21%
	Some College	67	26%
	College Degree	68	27%
	Graduate Training	65	26%
Income	<$50,000	75	30%
	$50,000-74,999	42	17%
	$75,000-99,999	45	18%
	≥$100,000	65	26%
Religion	Protestant	79	31%
	Catholic	80	32%
	Jewish	17	7%
	Other	77	30%
Types of Cancers	Hematological Malignancies*	53	21%
	Prostate	31	12%
	Breast	30	12%
	Lung	21	8%
	Renal	21	8%
	Other§	96	38%
Number of Prior Cancer Treatments	0	89	35%
	1-2	76	30%
	≥3	88	35%
Phase of Current Research Study	I	53	21%
	II	24	9%
	III	104	41%
	Other	72	28%

* Hematological malignancies include both acute and chronic leukemias, non-Hodgkin's lymphoma, multiple myeloma, Hodgkin 's disease, and myelodisplastic syndromes.

[§] Other malignancies include lung, pancreatic, ovarian, colorectal, melanoma, brain, sarcomas, and other cancers.

° Percent may not add up to 100% due to rounding.

TABLE 2: Research Participants' Concern about Financial Ties between Researchers, Cancer Centers and Drug Companies

	RESEARCHER FINANCIAL TIES		CANCER CENTER FINANCIAL TIES	
	Start of Interview	End of Interview	Start of Interview	End of Interview
Very worried	1%	<1%	1%	0%
Somewhat Worried	6%	5%	7%	6%
A Little Worried	11%	17%	21%	21%
Not Worried at All	80%	77%	70%	72%

TABLE 3: Effect on Participation in the Current Research Trial of Financial Ties between Researchers, Cancer Centers and Drug Companies

	RESEARCHERS				CANCER CENTERS		
	Stock	**Consulting**	**Honoraria**	**Patent Royalty**	**Stock**	**Per Capita Payments**	**Patent Royalty**
No Effect on Participation	76%	75%	82%	70%	77%	83%	79%
Stop Participation	11%	12%	9%	14%	12%	9%	10%
Encourage Participation	1%	6%	4%	7%	2%	3%	3%
Other*	11%	7%	6%	9%	9%	5%	8%

***** Includes it depends, don't know how it would affect participation, and refused to answer.

TABLE 4: What Financial Ties between Researchers, Cancer Centers and Drug Companies should be Permitted?

	RESEARCHERS				CANCER CENTERS		
	Stock	**Consulting**	**Honoraria**	**Patent Royalty**	**Stock**	**Per Capita Payments**	**Patent Royalty**
Should be Permitted	64%	82%	81%	70%	57%	78%	72%
Permitted within Limits	8%	5%	5%	8%	9%	5%	7%
Absolutely Prohibited	27%	13%	13%	23%	34%	17%	21%

TABLE 5: Disclosure of Financial Ties between Researchers, Cancer Centers and Drug Companies

		Researcher's Financial Ties	Cancer Center's Financial Ties
To Whom Should the Disclosure of Financial Ties be made	**Research Participants**	35%	NA
	Cancer Center Administration	19%	NA
	Independent Oversight Committee	32%	NA
	Government Agency	3%	NA
	Researcher or Cancer Center should decide who to tell	6%	NA
	No one	2%	NA
	Other	2%	NA
What Should be Disclosed to Research Participants	**No Disclosure Required**	17%	16%
	Disclosure if Financial Ties above a Monetary Threshold	9%	6%
	Disclosure of All Financial Ties Regardless of Amount	31%	33%
	Disclosure of Oversight System for Financial Ties	40%	43%
	Other	2%	1%

E. Horstmann, C. Grady, M. McCabe, E. J. Emanuel; Phase I participants as a vulnerable population; *Journal of Clinical Oncology*, 2004 ASCO Annual Meeting Proceedings (Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004: 6059 Available at http://careers.jco.org/ac/1,1003,_12-002636-00_18-0026-00_19-001662,00.asp