

# Paying Fees to Referring Physicians

## Ethical or Not Ethical?

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When investigative sites are struggling with subject recruitment, and it is increasingly obvious that a study will not meet its enrollment timeline, study teams must generate new ideas to facilitate recruitment. Invariably, someone will propose paying noninvestigator physicians for referrals, while others will be adamant in their opposition to this practice. Those who oppose paying physicians for referrals believe that it violates widely accepted ethics codes and is an unallowable conflict of interest. At the other end of the spectrum, those who support paying referral fees to noninvestigator physicians are sometimes unaware of ethics codes that seem to outlaw this practice, or they have a different interpretation of what the ethics codes actually mean.

In the highly regulated world of clinical trials, how can some stakeholders strongly support payment for physician referrals while others hold the completely opposite opinion?

This article explores this topic, starting with why physicians are such a valued referral source, moving on to definitions of such commonly used terms as “referral,” “referral fee,” and “finder’s fee,” and discussing the services for which fees may be paid. Such fees may depend, for instance, on whether the physician is merely providing a patient’s name to an investigator or is doing more, such as engaging in the process of identifying and prequalifying a potential subject and having a conversation with that individual about a specific clinical trial.

The article highlights the amount of work that goes into creating a referral, and also looks at specific ethics statements related to compensation for referrals and how they may be interpreted. The discussion concludes with results of a survey on this subject, which was conducted at a session presented at the ACRP 2008 Global Conference. The survey was conducted twice—once at the beginning of the session and again at the end—to gauge participants’ opinions regarding various situations in which payment for referrals might be considered. Although attendees changed their responses somewhat following a discussion on this subject, what is noteworthy is that there was no consensus.

The subject of compensating physicians for referrals often evokes very strong feelings from clinical stakeholders either in favor of payment or against it; as a result, this article does not draw a conclusion as to the appropriateness of paying healthcare professionals for referrals. As consultants in the clinical research enterprise, the authors have experienced both viewpoints among their clients, and see a need to encourage discussion on this subject.

## Why Seek Referrals from Physicians?

It is well documented that patients look to their doctors as a trusted source of medical information.<sup>1,2</sup> Because of this special relationship, they have a key role to play in providing information to patients about their healthcare options, including considering participation in a clinical trial. Research suggests that many patients prefer to learn about clinical trials from their physicians.<sup>3</sup>

Several Harris Polls surveys have addressed the issue of public awareness of clinical trials in the United States and how people learn about them. The most recent survey of 2,261 adults indicated that 38% of respondents cite the media as their main source of information about clinical research studies, yet slightly more than half (51%) state that they would prefer to learn about research studies from their regular physician. Moreover, 47% said they would be likely to participate in a study if their doctor recommended it,<sup>4</sup> and 79% claim that they would be very or somewhat likely to consult with their regular physician before agreeing to participate in a clinical trial that he or she is not conducting. This high percentage shows the value that patients place in their physicians' judgment, particularly if the patient has minimal knowledge of the clinical trial process.

With this level of trust as a background, the question arises as to whether it is ethical to pay physicians

or ethical for physicians to accept payments for referring patients from their practice to a clinical trial in which they are not participating. Some clinicians are reluctant to refer patients in exchange for compensation because they may believe that it is illegal or not allowed, are too busy to engage in this practice, or fear losing patients from their practice. Similarly, some investigative sites and study sponsors are unwilling to pay outside physicians for referrals because management and investigators believe it is not permitted, resulting in the implementation of standard operating procedures (SOPs) that prohibit this activity.

### Start With Definitions

There are no universally accepted definitions for "referral," "finder's fee," and "referral fee"; these terms tend to be used interchangeably, and seem to apply to investigators and noninvestigators alike. However, definitions can be structured from a compilation of sources, such as dictionaries and regulatory and ethical guidelines.

For the purposes of clinical research, a referral may be defined as the act of sending a patient to an investigator to learn more about a clinical trial and to be evaluated for suitability for participation. To make this referral, a noninvestigator physician does more than simply refer a name. He or she must first be aware of the clinical trial and have some knowledge of the inclusion/exclusion criteria in order to approach appropriate patients. Getting to this point implies that the physician has spent time learning about the study, prescreening the patient according to the preliminary eligibility criteria, talking to the patient about it, and providing contact information for the clinical trial site.

In this case, the physician clearly is doing more than forwarding a name to an investigator; so is it ethical to pay a referral fee for this work? If so, how much is an appropriate yet not overly incentivizing fee, and should the referring physician be paid only if a subject

actually enrolls? And must the referring physician disclose to the patient that he or she is receiving compensation (either in the form of money or gifts) for making the referral?

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It might be helpful to distinguish between a finder's fee and a referral fee:

- A *referral fee* is compensation paid to a healthcare provider who identifies a patient as potentially eligible for a trial and who provides information to the patient about the trial. The healthcare provider then forwards the name to the investigative site or offers the contact information to the patient. Compensation is paid to the provider whether or not the potential subject actually enrolls in the trial. This fee is often considered as reimbursement for the effort done to prescreen a subject.
- A *finder's fee* is compensation paid to the referring physician for bringing the patient to the investigator for the clinical research transaction. Compensation is paid by the investigator to the referring physician for this matchmaking service and is in exchange for the name of a patient.

The difference between the two is the amount of work that is performed by the physician to determine a subject's eligibility and the level of engagement between the physician and patient. The referral fee suggests that the physician has performed more tasks as compared to the finder's fee, which infers that the referring physician has done little more than hand over a name to an investigator.

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## Ethics Statements

These definitions can be used to help interpret the meaning of various ethics statements that address payment for referrals:

- **Council on Ethical and Judicial Affairs of the American Medical Association (AMA)**—Clinics, laboratories, hospitals, or other healthcare facilities that compensate physicians for referral of patients are engaged in fee splitting, which is unethical. . . . Offering or accepting payment for referring patients to research studies (finder’s fees) is also unethical.
- **International Code of Medical Ethics**—A physician shall not receive any financial benefits or other incentives solely for referring patients or prescribing specific products.
- **American College of Physicians Ethics Manual**—Giving or accepting finder’s fees for referring patients to a research study generates an unethical conflict of interest for physicians. Compensation for the actual time, effort, and expense involved in research or recruiting patients is acceptable; any compensation above that level represents a profit and constitutes or can be perceived as an unethical conflict of interest.

According to Opinion 6.03 of the AMA code, it is unethical for physicians to receive any kind of compensation in return for referral of patients to healthcare facilities, which covers referral fees for research studies, since these studies must be conducted in a healthcare facility. Opinion 6.02 refers to this practice as fee splitting.<sup>5</sup>

Similar to the AMA code, the International Code of Medical Ethics takes the position that physicians are not to be compensated for referring patients to research studies; however, from the wording, there is no way to determine if “referrals” means simply forwarding a name or engaging in additional work performed on behalf of the study. By comparison, the Ethics Manual from the American College of Physicians is more

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specific; it, too, states that compensation for referring a name is unethical; however, it goes on to say that compensation is acceptable if a physician does more than forward a name—if he or she actually invests time and effort in recruiting potential subjects.

Clearly, the intent of these statements is to curb conflict of interest for

healthcare professionals whose unbiased judgment may be affected by hefty payments at the expense of doing what is best for the patient. Yet, is it a conflict of interest to pay for work that has been performed, especially if the referring professional plays no part in the informed consent process or in enrolling subjects?

The literature has numerous articles on the coercive nature of incentives for enrollment of study volunteers into clinical trials, often targeting investigators who refer patients from their own practices into studies they are conducting. In one article, Lemmon and Miller refer to “finder’s fees” as offers of money to health professionals in reward for their referral of patients eligible for research participation, over and above reasonable remuneration for services rendered.<sup>1</sup> In another of their articles, they state that finder’s

**Table 1** Arguments for and Against Payment for Noninvestigator Referrals

| Arguments in Favor of Payment   | Arguments Against Payment   |
|---|---|
| <p>The amount of time required is substantial for a noninvestigator physician to refer a patient to a clinical trial, as it includes:</p> <ul style="list-style-type: none"> <li>• Reading or hearing information about specific trials</li> <li>• Identifying key eligibility criteria and reviewing charts to identify potential subjects</li> <li>• Explaining the clinical trial process to the patient, and explaining that the investigational drug may not necessarily work better in treating the patient’s condition than what he or she is currently using or that the patient could receive placebo</li> <li>• Providing contact information to the patient</li> </ul> | <p>May make highly ethical physicians feel uncomfortable, and possibly deter them from referring for fear of appearing to be seeking financial gain, as opposed to seeking what is best for the patient</p> |
| <p>Possible increase in the number of subjects referred by physicians to clinical trials if some sort of compensation is available</p>  | <p>Incentives may affect a researcher consciously or subconsciously to coerce or steer subjects into participating in research, thereby compromising the integrity of the research or researcher</p>        |
| <p>Participants can be made aware of referral payments received by physicians</p>   | <p>Such fee arrangements are not generally disclosed to the patient</p>   |
| <p>Part of the physician’s role is to present treatment options to a patient, and referring a patient for research participation may require more work than referring that same patient to existing treatment options</p>   | <p>If no work is being done by the referring physician other than to pass along contact information to a patient about a trial and/or an investigator, then there should be no fee exchanged</p>            |

Source: Clinical Performance Partners and Sherry Reuter & Associates, 2008.

fees are for the “mere recruitment of research participants,” without defining what work, if any, is done by a noninvestigator healthcare professional to “merely” recruit potential subjects.<sup>6</sup> With the overall view of referral payments decidedly negative, and with no differentiation between payments to investigators and noninvestigators, it may add greater clarity to the discussion if the two are separated. With that step taken, it is possible to explore the positive and negative aspects of payments specifically to noninvestigators (see Table 1).

### The Value of Interactive Discussion

From the outset, institutions and clinical trial stakeholders have deeply entrenched opinions and practices about paying noninvestigator physicians for referrals. As discussed, the clinical research enterprise is split into two camps, causing a lack of consensus and inconsistent practice. Each camp fails to understand the rationale of the other, and both operate without consideration for other views on this hot button topic.

This diversity of opinion was revealed in a survey conducted during a session at the ACRP 2008 Global Conference in Boston, Mass. The authors presented a session entitled “Regulatory and Ethical Considerations in Paying Physicians for Referring Patients to Clinical Trials.” As part of the session, attendees were surveyed as to whether it would be appropriate and ethical to pay noninvestigator physicians for referrals under a variety of circumstances; approximately 50 attendees participated in the survey.

A sampling of the discussed scenarios included:

- The appropriateness/acceptability of paying nonstudy physicians a finder’s fee for every patient they refer to the study site as long as this is disclosed to the patient.
- The appropriateness/acceptability of reimbursing nonstudy physicians for the time spent reviewing charts and contacting

potential patients about a study opportunity.

- The appropriateness of paying referring physicians only if the patients they refer are randomized into the trial.
- The appropriateness of paying referring physicians for their time in prescreening patients (e.g., conducting chart reviews, prescreening activities that are done as part of the standard of care, speaking to patients about the study, etc.) only if they are listed on the U.S. Food and Drug Administration’s (FDA’s) Statement of Investigator Form 1572 as a subinvestigator.

Participants were surveyed twice—at the beginning of the session and then again after discussion—on the ethics statements and various interpretations of terms such as “finder’s fee,” “referral fee,” and “referral.” There was a shift in opinion following the session, as participants were invited to think critically about the various statements and how they could be interpreted. Ultimately, there was no consensus as to whether it is ethical to pay referring physicians.

This change of opinion is highlighted in three examples of survey results. In Figure 1, respondents were asked if it is appropriate to pay referring physicians only if they are listed on the Form 1572. Before training, 61% of respondents responded “no,” but this figure jumped to 73% after training. Some respondents might have con-

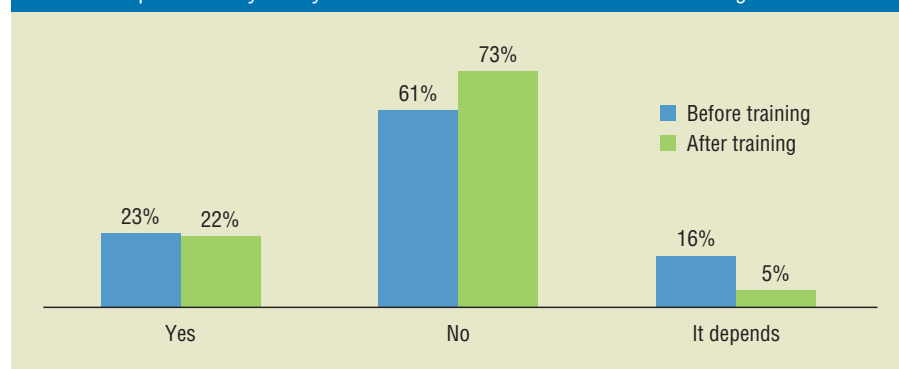
cluded that noninvestigators could ethically receive payment for referrals without being listed on the 1572. Second, they could have determined that the noninvestigator physician could not ethically be listed on the 1572 because in most cases, he or she would have insufficient knowledge of the specific study or of the relevant requirements of the FDA’s Good Clinical Practice guidelines.<sup>7</sup>

*There was no consensus as to whether it is ethical to pay referring physicians.*

Figures 2 and 3 also show changes in opinion following training. The issue in Figure 2 is the appropriateness of reimbursing physicians for reviewing charts and contacting patients about the opportunity. Prior to the training, 68% believed that compensation is appropriate in this circumstance. Post-training, when respondents considered the work involved in performing these tasks, a higher percentage (74%) deemed it acceptable.

The results in Figure 3, which addresses the appropriateness of paying referring physicians only for patients who are eventually randomized, suggest that respondents may have focused carefully on ethical statements, as the share who believed that “it depends” dropped from 7% before

**Figure 1** Is it appropriate to pay referring physicians for their time in prescreening patients only if they are listed on the Form 1572 as a subinvestigator?



Source: “Regulatory and Ethical Considerations in Paying Physicians for Referring Patients to Clinical Trials,” paper presented at ACRP 2008 Global Conference & Exhibition.

training to zero after training. This also suggests a greater understanding that compensation is for work done to prepare a referral and should not be linked to eventual randomization.

After the training session, some attendees reported that, as a result of the training, they moved from a knee-jerk reaction of “we can’t pay for referrals” or “our SOPs prohibit us from making payments for referrals” to a more thoughtful approach in which the subject can be carefully examined.

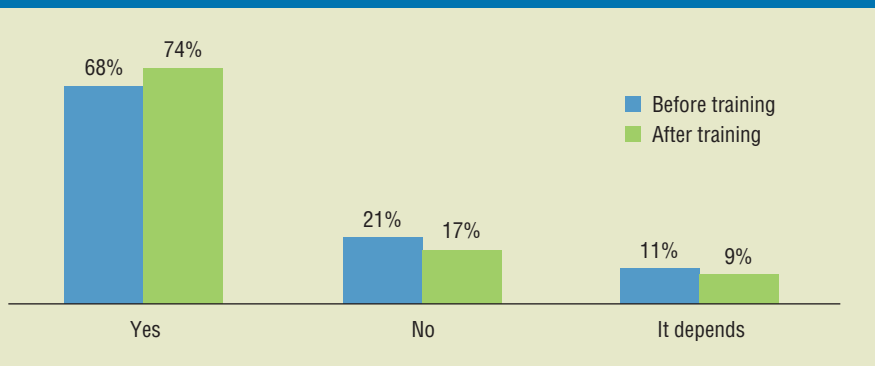
### A Closer Look

With the continuing challenge of patient recruitment, it is important to explore whether there is an ethical way for physicians to inform potentially qualified patients about clinical trials, prescreen them, and be reimbursed for their time and effort. The link to outside physicians is critical, as they are viewed by their patients as a trusted source of medical information.

Currently, there are ethics statements from various organizations that discourage finder’s fees, but no established mechanism within the clinical research enterprise to explore unresolved issues tied to this subject. In the absence of broad consensus across the research community, some stakeholders have established their own guidelines regarding compensation for referrals. As an example, one academic institutional review board (IRB) has put forth a statement that explicitly discourages payment of finder’s fees for the purposes of patient recruitment.

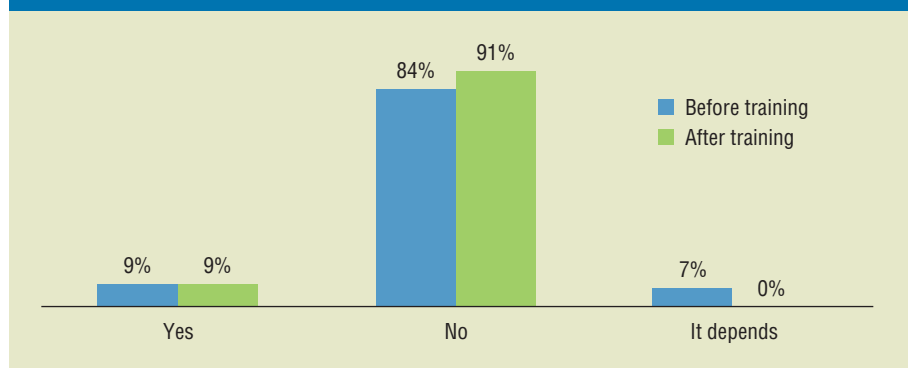
*It is important to explore whether there is an ethical way for physicians to inform potentially qualified patients about clinical trials, prescreen them, and be reimbursed for their time and effort.*

**Figure 2** Is it appropriate/acceptable to reimburse nonstudy physicians for the time spent reviewing charts and contacting potential patients about a study opportunity?



Source: “Regulatory and Ethical Considerations in Paying Physicians for Referring Patients to Clinical Trials,” paper presented at ACRP 2008 Global Conference & Exhibition.

**Figure 3** Is it appropriate to pay referring physicians only if the patients they refer are randomized into the trial?



Source: “Regulatory and Ethical Considerations in Paying Physicians for Referring Patients to Clinical Trials,” paper presented at ACRP 2008 Global Conference & Exhibition.

The IRB states in its guidelines, however, that in some cases, it may be acceptable for investigators to offer nominal payment to noninvestigators if the board can be assured that the person who receives that incentive will in no way encourage subjects to enroll in a study, and that applicable laws are not violated.<sup>8</sup> According to this IRB, each case must be considered individually, and payment to outside physicians should be structured as a contract, with payment providing reimbursement for actual services rendered by the physician or his or her staff for recruitment purposes. If compensation is permitted by the IRB, it should be paid whether or not a subject enrolls in a study.

Another IRB has reconciled this dilemma in a similar fashion, by

adopting a model that is consistent with common medical practice in the U.S. when surgeons request medical consultations by referring primary care physicians as part of the preoperative evaluation. This preoperative medical consultation performed by the primary care physician is paid for by the patient or insurance company. In the case of a clinical trial, if the investigator requests a specific service in writing (e.g., medical consultation) from the referring physician to be performed on behalf of the study, then the referring physician would be reimbursed by the investigator for this referral consultation service.

It behooves the clinical research enterprise to explore approaches such as this in determining if there are ethical ways of including and compensat-

ing outside physicians in the continual search for study volunteers. Currently, some companies and study sites are paying physicians for referrals, whereas others are adamant that it is unethical to do so. As the research community struggles with this issue, it should be discussed openly, and various viewpoints should be welcomed and critically evaluated. Only then would stakeholders on all sides of the question hear the rationale of others.

After an exchange of ideas and careful examination of all of the concerns, the stakeholders can better determine whether there is an acceptable way to integrate this practice into clinical trials. This would provide a background for informed decisions and more consistency in the practice of clinical research.

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### References

1. Lemmens T, Miller PB. 2003. The human subjects trade: ethical and legal issues surrounding recruitment incentives. *The Journal of Law, Medicine, and Ethics* 31: 398-418; available at [www.allbusiness.com/legal/3587010-1.html](http://www.allbusiness.com/legal/3587010-1.html), accessed January 2, 2009.
2. Arnold DE, Holm RP. 1996. The quantity and quality of medical information available to the public. *South Dakota Journal of Medicine* 49: 69-74.
3. Harris Interactive. June 2004. Public Awareness of Clinical Trials Increases: New Survey Suggests Those Conducting Trials Are Doing a Better Job of Informing Potential Participants of Opportunities. Available at [www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=812](http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=812), accessed January 8, 2009.
4. Harris Interactive. June 2005. New Survey Shows Public Perception of Opportunity to Participate in Clinical Trials Has Decreased Slightly From Last Year. Available at [www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=941](http://www.harrisinteractive.com/news/allnewsbydate.asp?NewsID=941), accessed December 31, 2008.
5. American Medical Association. Health and Ethics Policies of the AMA, [www.ama-assn.org/ad-com/polfind/Hlth-Ethics.doc](http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.doc), accessed January 8, 2009.
6. Lemmens T, Miller PB. 2006. Regulating the market in human research participants. *PLoS Medicine* 3:e330, available at [www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030330](http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030330), accessed January 2, 2009.
7. U.S. Food and Drug Administration. 21 CFR Parts 312.50, 312.53, and Sections 4.1 and 4.2 of the Good Clinical Practice Guidelines.
8. University of Pennsylvania, Office of Regulatory Affairs, Guidelines for Payment for Recruitment of Subjects in Human Research (Finder's Fees), April 21, 2006, available at [www.upenn.edu/regulatoryaffairs/Pdf/guidelinespaymentforrecruitment.pdf](http://www.upenn.edu/regulatoryaffairs/Pdf/guidelinespaymentforrecruitment.pdf), accessed January 5, 2009. **ACRP**

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