JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 6, No. 11, November 2010 "Can You Handle the Truth?"

Investigator Compensation by the Research Site

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How much can and should a research site pay an investigator for his or her contribution to a clinical study? Unfortunately, there are many variables and no simple formula.

To start with, investigators can have many different relationships with the research site. They may be the owner, an employee, on staff, or a contractor for one or more studies. For clarity, this article will discuss the scenario in which a site contracts with an independent physician (or other professional) to act as a principal investigator on multiple clinical studies.

Investigator Contributions

Investigators can contribute to studies in many ways, including the following:

- **Study conduct** responsibilities, such as obtaining informed consent, signing delegation of authority logs, reviewing laboratory reports, performing study assessments, and managing subject health issues
- **Subject recruiting** responsibilities, such as contacting and influencing patients who might enroll in the study
- **Medical care** responsibilities related to reporting adverse events and addressing subject health issues
- **Regulatory** responsibilities, especially signing the FDA 1572 form, which has legal consequences
- **Business** responsibilities related to the clinical trial agreement and other study contracts
- **Legal** responsibilities, including potential liability for subject injury
- **Management** responsibilities, such as creating, training and supervising the study team
- **Sales and marketing** responsibilities related to evaluating and securing studies for the site
- **Financial** responsibilities related to compensating personnel, providing the equipment and facilities, etc.
- **Institutional** responsibilities related to sponsoring the study in the organization
- **Reputational** responsibilities related to lending one's reputation to the study, which is especially significant for key opinion leaders

Compensation Principles

Investigator compensation should have the following characteristics:

- **Motivational.** Compensation must be acceptable to the investigator and structured to efficiently incentivize performance without creating legal or ethical issues.
- **Affordable.** Study budgets impose limits. If the budget is tight or site costs are high, it may not be possible to compensate the investigator and everyone else adequately.
- **Legally compliant and ethical.** Excessive compensation might encourage investigators to over-enroll and over-retain subjects. Excessive compensation can run afoul of the U.S. False Claims Act, the Stark Law, the anti-kickback statute, various state laws, and codes of ethics.

- **Fair.** Compensation should be proportionate to contribution. Experienced investigators with proven high performance should earn more than new investigators. Fairness is not just an ethical issue. Compensation that is unfairly low may be unsatisfactory to the investigator. Compensation that is unfairly high may be economically unaffordable or objectionable to others. In general, information about compensation should be kept confidential. However, it is best to set compensation on the assumption that the information will leak out. If compensation for two investigators differs, be prepared to explain the difference.

In 2009, physician annual salaries ranged from a low of $176,974 for pediatric pulmonologists to a high of $641,728 for spinal orthopedic surgeons, with a median of $278,000 and substantial regional differences.[1,2]

The Site's Financial Context

Financial compensation must be considered in the site's larger financial context:

- How much revenue will the study generate?
- How profitable will the study be after all costs are considered? What are the profitability objectives?
- Is the organization willing and able to subsidize money-losing studies to accomplish other objectives, such as patient care, staff retention, and marketing?[3]
- When can the organization pay compensation, given how slowly most sponsors pay?
- How much financial risk is the organization willing to take?

To answer these questions, the site should review the relevant financial statements: statement of profit and loss, balance sheet, and sources and uses of cash.

Compensation Structure

The structure of investigator compensation is very important. At one extreme, the site could pay the investigator a fixed fee for the study, regardless of his or her contributions. A similar option is to pay the investigator a percentage of study revenue or profit. At the other extreme, the site could pay the investigator for specific services performed or time spent. The first two options have the advantage of being very simple. The third option is more time-consuming to administer, but strongly motivates the investigator to perform the required services.

The most accurate approach is probably a hybrid system that rewards the investigator for his or her contributions and is consistent with the financial success of the study, but does not cross any ethical lines and is not too complex and time-consuming to administer. For example, start-up costs are fairly consistent from study to study, so they could be compensated in the form of a fixed fee. Study procedures vary based on the number of procedures performed, so they could be compensated in the form of procedure fees. A percentage of revenue or profit could be added, based on the financial success of the study. These formulae may not capture the investigator's contribution or the reality of the study, so some management discretion is advisable to penalize slackers and reward performance above and beyond the call of duty. However, a simpler approach may be better, with the understanding that compensation will be adjusted from study to study based on performance.

Whatever the compensation structure, it is essential to document it clearly and expect imperfections that will have to be addressed over time. When designing the compensation structure, assume that physicians, like most people, will act to maximize their income while minimizing their work. With this approach, unpleasant surprises will be minimized.

Negotiating Compensation

Compensation is often the subject of negotiation, a process in which the parties determine whether they can agree on mutually acceptable terms. In a negotiation, each party has wants and needs that define the negotiation space. For example: “I need $800 but want $1,000.” If there is a gap between the “needs” positions, competent negotiators will not be able to reach agreement unless they can reframe to negotiation to include other wants and needs. However, if there an overlap, the only question should be who gets more of their wants.

The absence of a negotiation may mean that the site has made a “take it or leave it” offer that the investigator is free to accept or reject. (The offer can also be from the investigator to the site.) “Take it or leave it” offers are perfectly legitimate. They have the great advantages of being quick and simple. However, they must be properly designed in advance.

Not all compensation is financial. Physicians participate in clinical studies for many reasons other than direct cash payments. These reasons might include patient care, career advancement, intellectual stimulation, reputation and self-esteem. These other factors are often relevant to compensation negotiations.

It is therefore essential to understand the investigator’s motivations and the contributions he or she is likely to make. If compensation is set too low, the investigators will likely decline the offer, or accept it and later lose interest, perhaps permanently. If the compensation is set too high, it is difficult to take back what the investigator now considers his or her personal rights and property. Therefore, it is important to explicitly state, in writing, both parties’ expectations for contribution and how over- or under-achievement will be handled.

The more powerful party in a negotiation is likely to obtain better terms. To a large extent, power is based on contribution, but one party may just have a stronger personality or influence with management unrelated to study contributions. On the other hand, one party may just be an inept negotiator or not care much about the result. When power plays a significant role in the negotiations, problems caused by unfairness are likely to arise sooner or later.

Every negotiation takes place in the context of options. In financial matters, these options have “opportunity costs.” The question is always: “If I make this agreement, what other opportunities am I sacrificing?” For a practicing physician, the other opportunity is usually clinical care, but there might be opportunities like learning a new procedure, bringing a new medical service in house, or playing more golf. For the site, the most likely questions are: “What will a different investigator cost?” or “What is the cost of not doing these studies?” The technical negotiation term is “BATNA”: Best Alternative to a Negotiated Agreement.[4] In other words, a negotiator should compare a proposed opportunity with his or her second-best opportunity (including doing nothing at all).

Negotiation is not the same process as bargaining. Bargaining occurs when the parties trade offers, typically prices, without justification. “Split the difference” is a common result. Negotiation (“principled negotiation”) occurs when the parties explain the rationale for their positions, e.g., “I was a top enroller in my last 10 studies.” Negotiation is generally more time consuming than bargaining, but, by elucidating the rationales, it can often identify “win-win” solutions.

Referring Physicians

It is inappropriate and perhaps illegal to pay physicians a bounty for delivering patients to a study. The problem is that such compensation gives physicians a direct financial motive for doing something unethical because it is not in the patient's best interests. However, there is nothing unethical about paying a referring physician reasonable fees for services, provided the payments are not contingent on the patient enrolling in the study. For example, it is legitimate to pay the physician to read the protocol, discuss the study with patients, and perform the initial screening procedure (as a subinvestigator). Another option is to pay the physician for procedures after the patient enrolls in the study. This approach is contingent on the patient enrolling, which raises ethical issues. However, the same issues apply to the principal investigator, so other factors, such as the level of compensation, should be considered. It is impossible to eliminate all conflicts of interest. Any referral-related compensation should be consistent with normal procedure fees and hourly rates.

Subinvestigators

Subinvestigators can play various roles in a study, somewhere between principal investigators and referring physicians. Fee-for-service compensation works relatively well. However, such compensation can add up when preparation, training and administrative time is considered. These supporting activities can be paid per activity, with a fixed fee, or built into fee-for-service pricing.

Like referring physicians, subinvestigators are usually less engaged with clinical studies than principal investigators, and so are likely to disappear if they become dissatisfied with their compensation.

Conclusion

It is important to get investigator compensation right, but there are many factors to consider that can shift over time. By making the effort to understand and openly discuss these factors, the parties can create a successful and robust relationship.

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