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Developing an Investigator Compensation Plan

By Matthew Gibson

Before a site develops a compensation plan for a principal investigator or sub-investigator, it should determine its objectives for the investigator. These objectives might include the following:

- Serve as a principal investigator, with all the attendant responsibilities
- Serve as "principal investigator of record," with most responsibilities delegated to others
- Potentially develop into a principal investigator
- Work on one or multiple studies
- Perform specific procedures, assessments or other functions
- Be available as a back-up or extra set of hands
- Add capacity to the site or expand the site into a new therapeutic area, geographic area, or patient population
- Refer patients to a specific study or to multiple studies
- Attract studies to the site based on reputation and industry connections
- Train or mentor other investigators or other study personnel
- Help attract additional investigators in the future

A site should also attempt to understand the investigator's objectives, such as the following:

- Financial remuneration
- Involvement in research activities
- Experience with new therapies
- Time away from the routine or stress of clinical care
- Access to studies for his or her patients
- Introductions to new patients for her or her clinical practice
- Access to speaking or consulting opportunities with study sponsors
- Professional growth
- Networking

Some of these objectives might not have occurred to the investigator.

Do not assume that what you consider a burden is unappealing to an investigator. He or she might really enjoy reading protocols or even traveling to investigator meetings.

A site should also consider other factors, such as the following:

- What are the study(ies) characteristics, e.g., how complex is the protocol, how stringent are the requirements, and what is the visit schedule?
- What are the investigator's pertinent skills and experience?
- How much training will the investigator need?
- How much of the investigator's time will be required, and when?
- How much support will the site provide to the investigator because of the investigator's level of experience, the site's business processes, or other reasons?
- How does the investigator's personality fit with the site's culture?

- What are the logistical considerations, e.g., will the investigator be able to visit the site on a reliable schedule or on short notice?
- Will the investigator make contributions to the site beyond conducting studies?
- Is the investigator's perspective on the opportunity short term or long term?

The Compensation Plan

With the above information in hand, a site can start developing a compensation plan for the investigator. A sound compensation plan will have the following six characteristics:

- **Fair.** The compensation plan should fairly reward the investigator for his or her contributions.
- **Motivational.** The compensation plan should motivate the investigator to perform his or her tasks in a professional manner and motivate the site to utilize the investigator.
- **Affordable.** The site should be able to afford the compensation plan, given the revenue generated.
- **Practical.** The compensation plan should not be confusing, overly complicated, or difficult to administer.
- **Legal.** The compensation plan should comply with applicable laws and regulations.
- **Agreeable.** Both parties should agree that the compensation plan makes sense.

Fair Compensation

A fair compensation plan considers the investigator's contributions to the site and how other investigators (inside and outside the site) are compensated for similar contributions. The investigator will also compare the compensation plan to his or her alternative sources of income, typically from clinical practice, which varies widely by therapeutic area, type of employer, geography and other factors.

The investigator might overstate (knowingly or not) his or her rate of compensation for providing clinical care, for example, by understating non-billable time, e.g., dealing with insurance companies and patient emails. Minimizing the amount of time the investigator spends on study paperwork simplifies the comparison and is probably very appealing to the investigator.

Fair compensation reflects differences in the investigator's level of responsibility and oversight in clinical research vs. clinical care. Signing an FDA Form 1572 takes only a minute but involves a high level of responsibility. In contrast, a protocol might require the investigator to perform simple procedures that would be performed by a nurse in his or her clinical practice. Insurance is an important consideration, especially if the site plans to rely on the investigator's malpractice insurance, which might not cover clinical research.

Affordable Compensation

The compensation plan has to be affordable for the site. If the site cannot find studies that cover the cost of the investigator, it should not be contracting with him or her. Perhaps a different investigator would be more affordable. However, if the site is keenly interested in a specific study and only that investigator will do, the site, the investigator, or both will have to make the necessary adjustments. However, this approach is not sustainable in the long term.

Motivational Compensation

The compensation plan should motivate the investigator to perform his or her tasks in a professional manner. The compensation plan should also motivate the site to fully utilize the investigator.

A poorly structured compensation plan can motivate the investigator to do the wrong things. For example, paying the investigator a fixed fee for a study will not motivate him or her to enroll difficult patients. Paying the investigator by the hour will motivate him to spend lots of hours but not necessarily productively. Ideally, the compensation plan will provide exactly the correct level of incentives across the board, but see the section below on practical compensation.

Practical Compensation

To avoid the motivational problems with a poorly structured compensation plan, the site could define the investigator's responsibilities in fine detail and compensate him or her accordingly. Unless the investigator's responsibilities are very limited, this approach works better in theory than in practice for several reasons. First, it is time-consuming. Second, it provides lots of opportunities for quibbling. Third, it is confusing to administer for both parties. Fourth, each new study might require adjustments.

A better approach is to define the investigator's responsibilities at a moderate level of detail. The compensation plan should have enough detail so both parties fully understand, in good faith, what is expected. Periodic discussions can address any issues that arise.

A site can structure investigator compensation based on several different models, including the following:

- **Fixed Fee.** Pay investigator a fixed amount for a collection of tasks, e.g., those associated with study startup.
- **Retainer**. Pay investigator a fixed amount per month to be available to perform specified services, regardless of whether those services are actually requested.
- **Fee For Service (FFS)**. Pay investigator for services provided, such as patient screening, physical examinations, and clinical study assessments.
- **Relative Value Units (RVU)**. Like FFS except the payments are based on Medicare's Physician Fee Schedule of CPT codes.
- **Pay for Performance (P4P)**. Like FFS except payments are based on results, e.g., studies that are obtained from sponsors. Can create legal and ethical issues, e.g., if payment is based on patient enrollment.
- **Revenue or Profit Sharing.** Like P4P except the measured result is a study's revenue or profit. Can create indirect legal and ethical issues.

Investigators will view any proposed compensation plan through the lens of their employment history. Private practices, medical centers, community hospitals, urgent care centers, and other healthcare providers can employ different payment models.

In general, if an investigator is just performing specific tasks, such as study procedures and assessments, a fee-for-service model works well. If he or she is the principal investigator for a study with all the attendant responsibilities, a combination of fixed fee and fee-for-service model works well. Depending on the parties' objectives and characteristics, the other models can also be useful.

Legal Compensation

Compensation agreements must be consistent with fair market value and comply with the federal Anti-Kickback Statute, the False Claims Act, the Physician Self-Referral Law ("Stark Law"), and pertinent state laws. These complex laws are discussed in the article, "Investigator Compensation: Motivation vs. Regulatory Compliance," by Payal Cramer, in the September 2016 issue of this journal. Fair market value is discussed in the article, "FMV and the Market Failure in Clinical Research," by this author, in the July 2016 issue of this journal.

In addition, paying an investigator a finder's fee for referring a patient is generally considered unethical, as may be any pay-for-performance fee based on successfully screening, enrolling or retaining study participants.

Agreeable Compensation

Whatever the compensation plan, both parties must agree to it, preferably with enthusiasm.

If the investigator feels that the compensation plan is more than fair, he or she might contribute much more than that small extra amount. On the other hand, if the investigator feels that the site drove a bit too hard a bargain, he or she might scrimp on the services provided.

However, if the site feels that the investigator drove a bit too hard a bargain, it might distort the site's expectations of the investigator and even cause it to think about finding a replacement.

Discussing Compensation

Before discussing compensation with a potential investigator, it's probably best to determine the objectives, characteristics and factors listed above, as well as the specifics of the study or other work proposed. What is the study drug or devices? What are the study population and enrollment numbers? What are the timeline, procedures and workload? Once the parties agree that working together makes sense, they can then have an intelligent discussion about compensation.

Periodically, thereafter, the parties can discuss the compensation plan in the context of the ongoing relationship and make appropriate adjustments.

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