JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 13, No. 7, July 2017 "Happy Trials to You"

Effort-Based Salary Support for PI Oversight Charges

By Anita Bowler

Principal investigators (PIs) can contribute to clinical studies in six main ways:[1-3]

- They sign Form FDA 1572, assuming legal responsibility for conduct of the study.
- They lend their professional reputation to the study.
- They bring their patient relationships to the study.
- They assume responsibility for the safety and welfare of study participants.
- They contribute their time, energy and expertise to the entire study process, including reviewing the protocol, taking part in study visits, monitoring lab reports, and closing out the study. They might also contribute to study design and data analysis.
- They oversee and take responsibility for the work of the study team and any subcontractors.

A competent site manager, study coordinator, or other study team member can substantially reduce the PI's work but not his or her responsibilities.

The PI's time contributions fall into four categories:

- Those that take essentially no time, such as lending his or her reputation to the study
- Those that occur once during a study, such as reviewing the protocol
- Those that occur throughout the study's duration, such as weekly staff meetings
- Those that vary depending on the amount of activity on the study, such as interactions with study participants at study visits

Table 1 below presents a comprehensive list of PI duties that take time.

The structure of a study budget should reflect these four categories of PI contribution. Ignoring any of them will create a disconnect between the financial incentives and the desired contributions. In the simplest example, paying PIs a fixed amount for a study without regard for the number of participants enrolled will tend to generate studies without participants. Incentives for enrollment but not retention will generate studies with high enrollment and low retention.

Every study sponsor wants to compensate PIs fairly for their contributions, although the definition of "fairly" can vary widely. For example, one sponsor might focus on the time a PI spends on the study, another might give more weight to the PI's scientific reputation, another might focus on the PI's track record in conducting studies, another might take the economist's perspective of "what the market will bear," and another might consider the prescribing volume of the physician.

Table 1. Principal Investigator Oversight Duties (as Appropriate)

Start-Up • Participate in site qualification visit • Review protocol • Present to disease group • Present to Phase I program • Present to Protocol Review Monitoring Committee • Review billing grid • Attend investigators meeting • Submit conflict of interest form • Submit Office of Sponsored Projects proposal • Train on protocol, online and in person • Review informed consent form • Submit application to IRB • Sign off in university clinical trials billing system • Review and sign budget • Sign contract • Attend study initiation visit • Review patient database for feasibility • Complete their part of feasibility questionnaire • Review lab manual • Teach protocol to staff • Participate in Feasibility Review Committee • Approve treatment plan in electronic medical record • Answer IRB questions	• Submit application to Radiation Use Committee and answer questions • Submit application to Biosafety Committee and answer questions • Manage emails • Participate teleconferences **Open to Accrual** • Review adverse events • Sign off IRB amendments/ renewals • Meet with site monitor • Manage emails • Participate in teleconferences • Identify possible subjects • Participate in patient screening • Review and approve treatment plan revisions • Educate staff on protocol amendments • Manage dose modifications • Review lab reports • Review scans • Review electrocardiograms • Review mutation and response assessments • Coordinate patient procedures • Participate in consent process • Attend progress meetings • Review patient eligibility • Review and approve serious adverse event reports • Respond to subject phone calls	• Review and approve deviation reports • Review concomitant medications • Update electronic medical records • Coordinate subject home care • Answer billing questions Participate in audits • Correspond with sponsor • Approve data query responses • Answer Research Data Coordinator questions • Review subject charts • Complete Investigational New Drug (IND) safety reports • Review and approve case report forms • Oversee reconsent and education **Closeout** • Approve data query responses • Review IND safety reports • Attend closeout visit • Review and approve final letter to IRB • Participate in audit (including post-study) • Correspond with sponsor • Review and approve final case report forms • Write publication • Correspond with sponsor • Advise patients on post-study care

Some PIs are less motivated by financial compensation than others. For example, they might accept lower compensation for a scientifically interesting study or one that might help patients.[1-3] The PI's perspective on compensation also varies depending on the nature of the research site:

- If the PI owns the research site (or is compensated based on study revenue), he or she will probably focus on the bottom line, regardless of study budget details. He or she is also more likely to consider the financial risks and potential rewards of a study. For example, a PI who is confident that numerous study participants will enroll is likely to prefer a study budget structured on that basis.

- If the PI is compensated based on line items in the study budget, he or she will probably focus on those line items.
- If the PI is compensated based on an effort-based system, he or she will probably focus on the impact of the study on those measures.
- If the study does not affect the PI's compensation, he or she probably will be most interested (if at all) in how it affects the finances of the site, the department, or other members of the study team.

Study sponsors that know how a research site compensates the PI are more likely to structure and quickly negotiate study budgets satisfactory to the PI, the site, and the sponsor. (Fair market value (FMV) rules do not prohibit the use of different budget structures for different investigators.[4])

Example

Huntsman Cancer Institute (HCI) is a unit of University of Utah Health. HCI's Clinical Trials Office (CTO) manages an average of 442 active oncology clinical studies, with an average of six study participants in each study. The CTO's staff of 113 study coordinators, regulatory specialists, and other personnel supports 35 physician-PIs. Typically, PIs are physicians who carry full patient loads (including research patients) and spend extra time on clinical research paperwork and oversight.

Old System: Income-Based Salary Support

In the old system, physicians receive a base salary plus "clinic income," a share of the income generated by their contact with patients and study participants. Study budgets include line items for PI oversight activities, usually related to patient visits. PIs receive none of the income from these line items, but a percentage of this income is credited to their salary account and reduces the departmental obligation.

An accountant records an estimate of the actual time the physician spends on study oversight in HCI's research effort reporting system. The study budget line items related to PI oversight usually amount to about 1% of the PI's base salary, benefits and overhead. In comparison, the amount of effort reported per study for oversight is usually about 5%.

New System: Effort-Based Salary Support

An HCI physician conducting research can have 10-12 active oncology studies at any time. A typical study requires about 5% of a physician's time for oversight (plus patient interaction time).

In the new system, staff negotiates with the study sponsor to replace PI-oversight-related budget line items with an invoiceable, quarterly PI oversight fee. The fee is usually 5% of the physician's base salary, benefits and overhead — about five times the comparable amount in a typical sponsor's proposed study budget. The PI oversight fee starts when the first patient gives consent and ends when the last patient is off trial. The oversight fee is prorated for partial quarters. PIs continue to receive clinic income.

We adopted the new system in consultation with the physician-PIs. In addition to fair compensation, they place a priority on simplicity and predictability. The new system makes the simplifying assumption that the time it takes a PI to oversee a study does not vary with the number of patients in the study. Our PIs are accustomed to effort reporting for NCI grants, so the new system works more naturally for them.

To date, 15 studies from seven of 40 study sponsors have agreed to use the new system. Budget negotiation timelines are shorter. Budgets are more flexible. Administration of physician compensation is simpler and fits better into the effort reporting system. PIs are satisfied with their compensation and better understand how it is calculated.

References

1. "Investigator Compensation by the Research Site," Norman Goldfarb, Journal of Clinical Research Best Practices, November 2010.
2. "Developing an Investigator Compensation Plan," Matthew Gibson, Journal of Clinical Research Best Practices, September 2016.
3. "Investigator Compensation: Motivation vs. Regulatory Compliance," Payal Cramer, Journal of Clinical Research Best Practices, September 2016.
4. "FMV and the Market Failure in Clinical Research," Norman Goldfarb, Journal of Clinical Research Best Practices, July 2016.

Author

Anita Bowler, BS, CCRP, is Finance Operations Manager in the Clinical Trials Office, Huntsman Cancer Institute at the University of Utah. Contact her at anita.bowler@hci.utah.edu.

