

Clinical Research Compensation Consulting Services

According to OIG guidelines for PHS research recipients, the most critical compliance issue is the accurate reporting of research time and effort because the compensation for the personal services of researchers, both direct salary and fringe benefits are typically the major cost of a project. It is essential the portion of the researcher's compensation for particular projects be carefully structured and accurately reported. Also, all compensation must be justified based on reasonable fair-market compensation. An institution's implementation of a serious, meaningful and effective research compliance program requires a significant commitment of time and resources which should be supplemented by a periodic independent, external consulting review to insure the highest level of due diligence and compliance.

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Compensation for the personal services of Professional Investigators, both direct salary and fringe benefits, are typically a major cost of a research project. Compensation planning for research project's Principal Investigators and Medical Directors require a salary compensation model be based upon fair market value. The development of a compensation model should include an independent professional appraisal of the market place to establish comparability. Several factors need to be evaluated for the compensation analysis that are typically not identified or measured with other healthcare related disciplines. It is essential that the model for participating physicians demonstrate a reasonable market comparison for structuring the compensation. Bay Area Healthcare Advisors, LLC provides our clients, comprehensive studies and written opinions as to the market comparability of salaries and reasonableness of all salaries related to research. Our professionals have the necessary experience to perform these services within any research setting.

The development of the compensation model itself must take into account all aspects of the services performed by the participating principal investigators and associate investigators including:

- ◆ Compensation on a per subject basis
- ◆ Compensation for providing strategic planning or advisory services
- ◆ Compensation for physicians who serve as medical directors or other administrative positions
- ◆ Additional metrics such as hours, stipends, Medical Director requirements, and Internal Review Board ("IRB") responsibilities.

Bay Area Healthcare Advisors, LLC's professional staff has provided research consulting services to academic medical centers and community hospitals throughout the United States. More recently, James M. Cesare, President and CEO of Bay Area Healthcare Advisors, LLC, has served as lead consultant and interim Vice President for a Comprehensive Research cooperative involving a 500 bed southern California hospital and associated regional hospitals. The engagement involved restructuring and reorganization of the entire research department ranging from compensation restructuring to a Corrective Action Plan. (CAP) due to a federal investigation.



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