

Are Study Coordinators Exempt from Overtime Pay Requirements?

By Greg Hendershott and Heather Deixler

Introduction

As has been widely publicized, wage and hour litigation is an increasing problem for employers. A common lawsuit involves a claim for overtime pay by an employee who the employer had been treating as exempt from overtime pay requirements. This article examines whether study coordinators are generally exempt from overtime requirements under U.S. federal law.¹ The answer is that a typical study coordinator who has reasonably high authority to use independent discretion is likely to be exempt, however study coordinators who exercise little or no independent discretion are likely eligible for overtime pay.

Federal Regulations

The basic law is that all non-exempt employees are entitled to overtime pay of 1.5 times their regular rate for hours worked over 40 in a workweek. The Fair Labor Standards Act (FLSA) creates an overtime pay exemption for any employee employed in a bona fide executive, administrative, or professional capacity. The Code of Federal Regulations (CFR) further defines these terms and provides three different tests to determine whether an employee qualifies for any of the administrative, executive or professional exemptions. Table 1 presents the criteria for each of the exemptions under the FLSA, as further defined by 29 CFR 541. To qualify for an exemption, all of the criteria in a column must apply. The Department of Labor (DOL) administers the regulations.

Legal Analysis

Based on an analysis of typical responsibilities assigned to study coordinators, it appears that they will likely meet the salary and duties tests for the administrative exemption.² The median salary for a Clinical Research Coordinator in the United States is \$50,439, which translates into \$970 per week, according to a Salary.com survey.³ Thus, a study coordinator will likely meet the compensation requirement of at least \$455 per week as set forth by 29 CFR 541.200.

Also, a study coordinator is generally responsible for organizing all aspects of a clinical research study, ensuring that the study is run smoothly and efficiently, and that all records are properly organized and retained. Study coordinators have vast administrative tasks, which include maintaining records of all study visits, reporting all adverse events and serious adverse events to the Principal Investigator, maintaining complete and accurate source documentation, and maintaining all other required documentation the research study requires. Study coordinators must also coordinate all aspects of study subjects from the recruitment and screening of potential subjects, to obtaining informed consent, to retaining subjects once they are enrolled. Furthermore, study coordinators are responsible for scheduling and conducting study visits, dispensing medications and devices, and educating subjects on their use. It is also the study coordinator who in many cases serves as the liaison between subjects and investigators, keeping the investigators apprised of the progress of the study and communicating with subjects as their questions arise. In short, the study coordinator directs and maintains the "command center" for the entire

investigation. This type of “independent judgment” allows many study coordinators to meet another key element of exempt status.

Table 1. Exemption Criteria

Executive	Administrative	Professional
Compensated on a salary or fee basis at a rate of not less than \$455 per week.	Compensated on a salary or fee basis at a rate of not less than \$455 per week.	Compensated on a salary or fee basis at a rate of not less than \$455 per week.
Primary duty is management of the enterprise for which the employee is employed or of a customarily recognized department or subdivision thereof.	Primary duty is the performance of office or non-manual work directly related to the management or general business operations of the employer or the employer's customers.	Primary duty is the performance of work: (i) requiring knowledge of an advanced type in a field of science or learning customarily acquired by a prolonged course of specialized intellectual instruction; or (ii) requiring invention, imagination, originality or talent in a recognized field of artistic or creative endeavor.
Customarily and regularly directs the work of two or more other employees.	Primary duty includes the exercise of discretion and independent judgment with respect to matters of significance.	n/a
Has the authority to hire or fire other employees or whose suggestions and recommendations as to the hiring, firing, advancement, promotion or any other change of status of other employees are given particular weight.	n/a	n/a

Finally, in order for a study coordinator to effectively run a study, the study coordinator must exercise discretion and independent judgment in matters of significance. For instance, a study coordinator must exercise discretion in screening potential subjects for enrollment in the study. Additionally, study coordinators in many cases design administrative tools that will enable them to conduct the clinical studies efficiently, accurately and in compliance with all governmental regulations and guidelines. It is also the study coordinator's responsibility to train other personnel and medical staff so that they may be involved in the study. However, a study coordinator who merely follows rote procedures and records routine participant information would not likely be exempt.

There appear to be no federal cases specifically addressing whether study coordinators are exempt. However, on September 22, 1998, the U.S. Department of Labor, Wage and Hour Division, issued an opinion letter in response to a request for clarification from a clinical research firm that sought an opinion on whether their study coordinators should be given exempt or non-exempt status. The study coordinators preferred to be paid an hourly rate, and therefore be entitled to one-and-one half times their hourly rate for each hour worked in excess of the FLSA's 40-hour overtime threshold. Ultimately, the Department of Labor refused to proffer a definitive stance on the status of the study coordinators, stating that the firm had not included sufficient information, and further reminding the firm that “it is

the responsibility of the employer to make the determination on exempt or non-exempt employee status.”⁴

Conclusion

With the Department of Labor’s opinion letter in mind, employers have some flexibility in assigning exempt or non-exempt status to its employees, but based on the many administrative responsibilities that a study coordinator must perform to effectively run a clinical research study, especially those operating at a higher level of independence, and assuming that their salary meets the minimum requirements discussed above, a study coordinator will likely qualify for the administrative exemption under the FLSA. We emphasize that employers must analyze exempt status on a case-by-case basis, and not all study coordinators have the same duties and authority. Certainly, numerous study coordinators are likely non-exempt. In most cases, however, study coordinators will be exempt from overtime pay requirements. Again, each position must be considered individually under the law.

Notes and Sources

1. It is important to recognize that most states have their own overtime laws in addition to the federal laws. While the exemption analysis is often similar or identical under federal and state law, employers must analyze both in determining whether to pay overtime.
2. A study coordinator whose primary duty is supervision may also qualify for the executive exemption.
3. http://swz.salary.com/salarywizard/layouthtmls/swzl_compresult_national_HC07000365.html
4. DOL Wage and Hour Opinion Letter No. 2079 (Sept. 22, 1998)

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