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Ensuring that rules and regulations are met

an interview with
Lynda S. Hilliard

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COLUMNS

DEPARTMENTS

by Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC

Summer is a state of mind

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With summer upon us in a few weeks, you may be thinking, "What can I do over the busy vacation season with my research compliance program?" Every now and then, I have someone call me and ask what areas are most important for research compliance. As hot button items go, there are many that one can choose from to do a process review or a gap analysis. But a couple stand out if you want to get into a summer state of mind for compliance that doesn't take a large team in place to do!

Willenberg

Sites and principal investigators (PI) want their money from trials. Many times, there is a lack of structure around residual balances. This can be problematic if it is not tracked appropriately. Federal funds not booked toward a grant award must be returned. Sometimes you may find the accounting out of sync with what is actually left over at the end for a sponsored drug or device study. Problems can arise when physician payouts with left-over funds appear large without a policy in place. Remember that when remaining funds are to be moved to a discretionary fund, someone might decide that not invoicing anything to the study will create a higher pool of money at the end.

Knowing what a study truly costs starts with a coverage analysis at the pre-award point in time. This simple method to ensure you are covering your true cost is a must. Even when pricing a grant application for patient care costs, a coverage analysis can be beneficial. Cost accounting for grants is important, but for sponsored studies, so is accounting and funds distribution to the various ancillary services that provide support for the trial. Do not forget to apply sponsored studies funding to salary and effort for your research team members too, because this sometimes is missed. This is another quick review that can be done.

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Another area that you can easily review is the procedures that occur prior to informed consent. This can be done in combination with a small billing review during the screening for an inpatient study. Reviewing records for patients who have research-related activities while they are inpatients is a great way to find not only consent errors in your clinical practice, but in your billing practice as well. This review is quick to do for a small study and can provide insight into both regulatory and billing compliance.

Indulge in a summer state of mind in research compliance!