Exact Effort:
Establishing a Revenue Producing Activity account in order to charge exact effort expenditures on clinical trials, at a standard rate, in real time

Lisa Werning – Director of Clinical Research
werning@surgery.wisc.edu
608-265-6858

Ann Collura – Clinical Trials Accountant
collura@surgery.wisc.edu
608-265-2941

1. Identify Problem:
Solve effort system disparity by revising the effort allocation process for clinical trials

➢ Clinical Trial effort expenses were not consistent with actual time spent on projects.

➢ Clinical trial budgets pay for subject milestones; total budgets and effort expenditures fluctuate with enrollment and volume of interactions.

➢ Disparity between the effort certification system and clinical trial budget structure resulted in frequent effort re-allocations and numerous salary cost transfers on a large number of projects, which was a barrier to efficiency and caused a lag in accurate financial reporting.

➢ Clinical trial accounts were over- and under-charged; PI's were frustrated.

2. Develop Solution:
Create a Revenue Producing Activity Account to capture actual expenses and charge clinical trial accounts each month

➢ Establish a Revenue Producing Activity Account; pay all coordinator salaries, fringe benefits, supplies, and CME from this account.

➢ Develop a standard hourly billing rate for coordinator effort.

➢ Instruct research coordinators to track their time on specific projects in Grindstone (Epiforge Software).

➢ Use monthly Grindstone reports to bill coordinator time to appropriate study accounts in 30 minute increments, at the standard hourly billing rate.

3. Implement Changes:
Task research coordinators with time tracking and charge clinical trial accounts for exact effort using standard billing rate

➢ Coordinator time expenses are captured in real-time with a flexible, easy to use system.

➢ New system assures PI's that they pay for exact hours worked at a set rate.

➢ The improved process eliminates the necessity to submit a high volume of salary cost transfers to retroactively assign costs to appropriate projects.

➢ Charging each study account for the exact effort applied to the project each month has increased visibility into the amount of effort it truly takes to conduct clinical research.

4. Analyze Results:
Increased transparency gives insight into how much time is actually spent on each trial every month

➢ The ability to delineate the type of work a coordinator has completed, within their monthly time reports, is important data that can be used to analyze the work completed on each clinical trial.

➢ Real-time effort tracking eliminates the need to estimate effort allocations upfront and make changes after the fact. Time savings is realized at every angle.

➢ Principal Investigators can see exactly how much effort study coordinators spent on their projects in a given month. Increased transparency facilitates better conversations and understanding between everyone involved.

5. Future Improvements:
Time tracking data and financial reports will be useful for revising billing rate and negotiating budgets with sponsors

➢ Refine time tracking guidelines to capture details about coordinator work, revealing expenses to budget on future projects.

➢ Use time tracking reports to analyze Standard Budget Guidelines, identify necessary changes, and incorporate fee adjustments. Some areas we will examine include: external monitor visits, monthly screening, and protocol training.

➢ Use activity reports, along with identified barriers to enrollment, to improve research conduct strategy and discuss budget planning with investigators.

Department of Surgery
UNIVERSITY OF WISCONSIN
SCHOOL OF MEDICINE AND PUBLIC HEALTH