

Industry Sponsored Clinical Trial Post-Award FAQs

1. What is the most appropriate way to charge salary expense? Based on the per patient costs in the internal budget?
 - Salary charges to the study should tie to actual expended effort by the PI and coordinator.
2. What if the coordinator is actively working on the project but no patients have been enrolled?
 - When the coordinator expends effort on recruiting, but no patients are enrolled, the effort needs to be taken into account and charged to the study. The department can review and adjust the effort on a quarterly basis to capture the recruiting effort, just the same as PI effort.
 - If the actual effort expended appears to be higher than estimated in the internal budget, talk with RMG about requesting additional funding from the sponsor, or the possibility of stopping the study.
3. How do we account for the variation in effort as enrollment fluctuates?
 - Effort can be averaged over the academic quarter (October to December, January to March, April to June, July to September).
4. Who is responsible for deciding how effort should be charged to the study?
 - The PI quarterly certification of expenditures is an affirmation of the allocation of effort and charges to each study.
5. How are effort and salary costs for each study calculated?
 - The internal budget is generated by RMG with the cooperation of the PI and coordinator, who provide estimates of hours or percent effort needed to execute a study.
6. Should we charge the percent effort indicated on the internal budget?
 - The effort in the internal budget should serve as a guide to facilitate discussion with the PI about his/her level of effort devoted on a per patient basis. This is not the same as a research grant. (see question 1 above).
7. Who is responsible for tracking and providing information to properly invoice the sponsor?
 - The financial analyst should work with the coordinator to track patient completions, patient milestones, invoiceable procedures/items, amounts owed, payments received (including payments from monitors), and effort expended by study staff. Based on patient completions and milestones, invoicing is done through CRISP.
8. What if the financial analyst thinks that expenses are higher than indicated on the internal budget?
 - The internal budget is an estimate of costs, not actual charges. If the financial analyst observes a wide variance between the internal budget estimates and actual charges, it should be discussed with the PI and coordinator as soon as possible so rebudgeting can be attempted or additional funding can be requested.
9. What if the sponsor asks us to conduct additional tests or additional visit?
 - If additional funding is needed, RMG must be involved in any sponsored project. Contact your RPM or CTRPM. For clinical trials, a contract amendment is required so a contract officer in the Office of Sponsored Research will also be involved. Finally, an IRB revision usually is required in these instances

and the CT RPM will be sure that the consent matches the revised work scope and that the IRB has approved the revised protocol.

10. What do we do when the current salary does not match the salary in the internal budget due to salary increases?
 - The internal budgets from RMG include estimated inflation including 3% for salaries at 9/1. The study will be charged whatever it is the current salary, but the internal budget should account for inflation, if the project begin and end dates match the internal budget.
11. Why don't the patient care costs charged to the study match the internal budget? Doesn't the internal budget indicate my negotiated patient care costs?
 - The internal budget is an estimate, based on prices at the time the budget is created. RMG adds inflation 10% for laboratory, technical/hospital, and supply charges at 9/1, and 5% for pro-fees at 9/1. For both LPCH and SHC, the hospital will charge the current procedure price, with a research discount. Patient care costs are not fixed, so departments should expect annual cost increases. In addition, the research discount can vary over time. So it would be rare to see an exact match between the budgeted patient care cost and the actual charge.
12. We received a no cost extension on our study, but there was no change in the study protocol. What will that do to our budget?
 - Extra care should be taken during a no-cost extension as there may be a shortage of funds, since no inflation was budgeted for the additional effort that may be required during the extended performance period.
13. How should we charge PI and study coordinator salary for start up of the study?
 - Although studies vary, in general effort related to start-up would be expected to be charged to the study account within the period of performance or at the start of the study.
14. Do we invoice patient costs based on the rate in the sponsor's payment schedule or the Stanford internal budget? What amount does the sponsor pay?
 - All invoices to the sponsor for patient costs should reflect the amount negotiated and indicated in the sponsor's payment schedule NOT the amount in the internal budget. Because of the contingency built into the budget, invoices should be based on the payment schedule, which always is included in the contract and Notice of Award (NOA). The sponsor will pay based on the payment schedule and CRFs submitted.
15. Is there an easier way to reconcile payments stemming from data reviewed between a CRO and the study coordinator?
 - The financial analyst will need to work closely with the coordinator to track what has been submitted to or reviewed by the sponsor/CRO. See also question #7. The data that the sponsor reviews should reflect patient enrollment and completion, so payments should match patients' status. Close and frequent collaboration between the coordinator and financial analyst would seem to be a critical component of tracking and reconciling payments
16. How do we reconcile annual salary when not provided with the NOA?
 - Salary charged to the study should reflect actual % effort x actual salary including any supplements for the period under review. The internal budget calculations begin with current salary, but inflation is added to estimate salary increases. Thus there will be no direct "reconciliation" between the salary amounts in the NOA or internal budget versus the salary charged to the study.

17. How is salary calculated on the internal budget?

- A typical salary calculation for Year 1 would be current salary (including supplements) /12 x # months in the current fiscal year x % effort + 3% inflation if the budget period crosses fiscal year. A 3% inflation is also added on future years. Also, see Question #5.

18. How do we address errors on an NOA?

- Contact your OSR accountant for corrections in PTA set up. Contact the [Clinical Trial Contract Officer](#) (CTCO) who signed the NOA for other errors, such as total award amount or project end date. Contact information for OSR is available at <https://ora.stanford.edu/contacts>