

PI effort on Clinical Trials (Industry-Sponsored or NIH)

Additional Information for DoResearch

[Faculty Effort on Sponsored Research - FAQs](#)

Effort in General (Non-Clinical Trial)

Faculty are not required to charge or cost share effort in every active quarter of an award. However, some effort needs to be direct charged or cost shared during each year of the period of performance. This effort can be provided at any time within the year, but salary may not be direct charged if no effort is expended. It is the responsibility of the PI and department to track committed effort during the performance period of the award to ensure the original effort commitment to the sponsor has been met. (DoResearch FAQ#2)

Industry-Sponsored Clinical Trials

PI effort expended on Industry-Sponsored Clinical Trials is dependent on the patient enrollment and when the patient procedures are performed. PI effort is not required for those periods where there is no activity on the study and procedures on patients have not been performed. (DoResearch FAQ#6)

NIH funded Clinical Trials

PI effort on NIH funded Clinical Trials must still follow NIH guidelines. For example, if the faculty member is designated as key personnel on the NOA, any reduction in person-months committed on the proposal requires prior approval from the agency. Always read the NOA carefully, as some awards have minimum levels of effort.

This also applies to PI effort on subawards from a prime NIH funded Clinical Trial. Even if there is a “per patient budget”, if there was a committed level of effort to our direct sponsor (or PI effort is reported to the direct sponsor for the annual all personnel report), the PI would need approval from the direct sponsor to reduce his/her effort more than 25% from the amount committed.

If there was not a committed level of effort to our direct sponsor, then effort PI effort should be recorded similarly to an industry-sponsored clinical trial – based on patient related activities.