**What Should I Include in My Pharma/Industry Sponsored Budget?**

* IRB Fees - Should budget for the following (including those using an outside IRB):
  + New Study Review: $2,500
  + Continuing Review: $1,000
  + Modification: $500
  + Please refer to: <https://hsc.unm.edu/research/compliance/hrpo/investigators.html> for additional information on how these fees are invoiced from IRB.
* Non-refundable start up fees (4-5k at least): for time spent by PI and clinical staff on IRB review paperwork, other regulatory document completion, trips to investigator meeting, protocol review time, etc. (paid regardless of whether or not the contract/study goes forward). If sponsor won’t accept, try adding in coordinator/PI time for investigator meetings.
* Payment upon execution of the contract – if you can negotiate it, for other start up type costs
* Payment upon completion of study – do not tie this to a site visit, only to submission of all case report forms or data or termination of the study
* Per patient costs (tests, supplies, labor, 1% PI effort) (this will translate into the per patient reimbursement or the reimbursement for completed case report forms as determined by the sponsor - [see UH charges memo](https://hsc.unm.edu/common/docs/guidance-docs/uh-patient-care-rates.pdf))
* Payment for departments doing testing (e.g. Pathology, Radiology) – both the hospital fee and the professional fee
* Screen failures payments
* Unscheduled visit payments
* 28% F&A on total costs
* Document storage fees
* Pharmacy fees (include a start up fee and then a fee/prescription)
* Postage if needing to send things regularly to sponsor
* Publication preparation costs
* Investigator meeting time – for investigator and support staff ($750/per person, per meeting)
* Regulatory/administration time (adverse event reporting, etc) ($750 per 6 months)
* Remember: most time spent on studies is maintaining regulatory documents including review & submission of adverse events to HRPO – this adds up in a long term (1 year or more) clinical trial

**Pricing contact info (see memo for more information)**

* Procedures: Contact [Julie Alliman](mailto:jalliman@salud.unm.edu?Subject=Clinical%20Trial%20Pricing) ([jalliman@salud.unm.edu](mailto:jalliman@salud.unm.edu)) or [Bonnie White](mailto:bwhite@salud.unm.edu?Subject=Clinical%20Trial%20Pricing) ([bwhite@salud.unm.edu](mailto:bwhite@salud.unm.edu))
* Professional fees & CPT codes: contact the director of the unit/department in which the procedures will be performed to get the correct CPT code and professional fees associated with the procedure
* Wilda McDonough at Tricore does CPT codes for labs for the referral billing/guarantor numbers.

**For more information on clinical trials services at UNM:**<https://hsc.unm.edu/ctsc/services/>