Industry Funded Clinical Trial Budget & Payment Terms Guidelines & Information

Required items for industry sponsored or supported clinical trial budgets:

- Correct IRB fees for initial, continuing, project modification reviews. Check IRB Fee Policy to use the most current fee schedule.
- Research Pharmacy set-up, maintenance and dispensing fees are required if Research Pharmacy needs to be involved in the study. (See Research Pharmacy Services website for more information).
- OHSU’s F&A/Indirect Cost of 25% will be charged to all budget items except for IRB fees and Research Pharmacy set-up fees, so this must be the indirect cost amount represented in the budget. Some departments or divisions charge an additional department assessment above the 5% included in the institutional F&A rate, but these amounts should not be represented in the budget as institutional F&A (See OPAM’s Department Assessment Guidelines for additional information).

Payee information for industry sponsored or supported clinical trial agreements:

Payee: Oregon Health & Science University
Address: Oregon Health & Science University
Attn: Office of Proposal & Award Management
0690 SW Bancroft, L106OPAM
Portland, OR 97239
EIN: 93-1176109
Email: OPAM Revenue at spacash@ohsu.edu
Phone: 503.494.0355

* If sponsor requires payment by electronic funds transfer, please contact CTO-Contracting for bank account information.

Best practices for industry sponsored or supported clinical trial budgets and payment terms:

- IRB fees and Study start-up fees should be non-refundable and payable within 30 days of execution of contract, even if study is cancelled.
- Either advanced payment representing payment for a given number of completed patients, or a set amount is recommended. Advanced payment should be used until depleted; at that time, defined payment schedule starts. Advanced payment will be partially or fully refundable based on costs incurred - e.g., number of visits conducted, number of subjects completed. Advance payment should not apply to study start-up fees; these fees should be listed separately.
• If study involves research-related screening tests/exams, included in the budget should be payment for screen failures. If sponsor includes a cap on the number of screen failure payments, it should be sufficient to cover expected number of subjects that will fail screening.
• Payment schedules should be adequate to keep the study account from going into significant deficit during the course of the study.
• Time limits should be avoided for invoicing and payment disputes. If required by the sponsor, make the time period as long as possible and contingent upon the sponsor’s final payment or OPAM’s final accounting of the study.
• Payments can be based on concrete milestones, time periods, and CRF completion and/or monitoring. However, time based milestones generally should be no less than quarterly unless study warrants a longer period of time. If payment is based on CRF completion, try to have payment linked to CRFs submitted rather than when monitor visits, if possible. It’s appropriate to accept payment on CRFs collected, but try to include minimum frequency for monitoring visits (usually at least quarterly). If payment is tied to monitoring, include provision that if monitoring visits do not occur, sponsor will pay based upon CRFs received. Avoid payment milestones based on resolution of data queries.
• It is acceptable to agree to invoice for certain costs. It would be ideal to limit invoicing to those costs that are incurred on an “as needed” basis – e.g., consent translation, subject compensation for travel, IRB continuing review and modification, etc.
• Sponsor retention of final payment until after study is completed is acceptable. Amount should be approximately 10% of total budget, but more than 20% of total budget is not acceptable.
• Avoid sponsor not paying for ineligible subjects or subjects with protocol violations. If necessary, limit nonpayment to the procedure that caused the protocol violation, or payment for the data that is now unusable due to the protocol violation. Always indicate that payment should be made for protocol violations approved in advance by the sponsor.
• It is acceptable to agree that OHSU/PI will not receive payment from outside sources for anything paid by the sponsor.
• Do not accept limits on the use of money received from sponsor only to the conduct of the study. An agreement to return refundable unearned funds to the sponsor at the end of the study is acceptable, but do not agree to return unspent funds to the sponsor at the end of the study.