

Financing Clinical Trials – Appropriate Compensation and Allocation of Study Budgets

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Presenter Bio:

Scott is the Director of Clinical Operations at BlueTheory Clinical Trials. At BlueTheory, Scott and his team work with experienced clinical research sites across the U.S. and Canada to bring in new study leads, as well as help with budget and contract negotiations, receivable management, and other operational needs. He holds a Master's in Medical Science from Boston University, and previously worked as a Clinical Operations Coordinator for several years at a large dedicated research facility in Florida.

Financing Clinical Trials

- Payment Models for Investigators
- Best Practices for Negotiation and Allocation of Study Budgets



Payment Models for Investigators



Investigator Payment Models

- Three Different Approaches
 - Percentage-Based
 - Procedure-Based
 - Fixed Salary/Hourly Rates

Percentage-Based Model

- P.I. takes a set percentage of the incoming grant payments
- For any extremely extensive study (ex. many P.I.-required scales), apply the percentage to the average procedures and apply an overage amount to the additional procedures. (e.g. apply the 16% to the “average” procedures and apply an overage amount if more than two scales).

Percentage-Based Model

- Appropriate percentage varies depending on the P.I.
 - Generally kept between 16-22% depending on the therapeutic area/practice size.
 - Examples of what may be an appropriate percentage based on P.I. experience and the site's enrollment capability:
 - 16% = Retired/Novice P.I.
 - 18% = Experienced P.I.
 - 20% = Large Practice
 - 22% = Experienced P.I. w/ Large Practice

Procedure-Based Model

- Establish a flat rate fee for each (applicable) study procedure.
 - Calculate the appropriate budget using the percentage method and distribute across the applicable procedures.
- First deduct non-applicable fees from the total grant payment prior to calculating percentage amount:
 - Diagnostic Procedures
 - Subject Stipend
 - Sub-Investigator Procedures (e.g.; required un-blinded procedures)
 - Sub-Investigator Payment

Procedure-Based Model

- Only procedures completed by P.I. (e.g., Physical Exam, ECG, etc.) would apply.
 - Non-reimbursable screen fails or unscheduled visits would not apply
 - P.I. fee applies for each visit even if procedures completed by sub-investigator.
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Percentage-Based

- Pros
 - Payment to P.I. is proportionate to incoming study revenue.
 - Simpler accounting method.
 - Shared risk.
- Cons
 - Can be difficult to understand the value of each procedure w/ abstract percentage.
 - Payments may be in excess of what would be commensurate w/ the work performed.

Per Procedure

- Pros
 - Limits reimbursement to actual work performed (no overhead).
 - Provides a real-time understanding of the value received for each procedure.
 - Procedure rates can be flexible as needed to meet the total goal percentage.
- Cons
 - More complicated system for accounting tracking.
 - Discrepancy in rates study-to-study becomes more apparent.

Salary/Hourly Models

- Fixed salary/hourly Rates
- Establish a flat hourly rate or salary depending on the physician's specialty.
- Structure the job duties to cover all P.I. responsibilities: IM meetings, SIVs, audits, emergency patient calls, etc.
- Range: \$100.00-\$250.00 depending on experience, specialty, volume of patients, etc.

Salary/Hourly Models

- Additional “Chart Review Fee” for subjects identified directly from the P.I.’s practice.
 - Cons: fixed salary, more risk for the site
 - Pros: more cost-effective depending on the volume of patients seen at the site.
 - More upside potential for the site- as long as number of patient visits is sufficient.
 - More beneficial for established sites.

Example PI Payment Schedule

SCHEDULE A P.I. Pay Schedule

Procedures	Number of Visits	Rate	Total Per Subject
Physical Exam	3	\$150	\$450
ECG	1	\$35	\$35
PI Fee**	11	\$125	\$1,375
Labs	3	\$15	\$45
CGI	2	\$50	\$100
Total Completed Patient Amount			\$2,005
Number of Patients Required	10	\$2,005	
Total Projected Income			\$20,050

Screen Fail subject visits will only be reimbursed to P.I. if reimbursed by the Sponsor.

Early Term subjects will be paid on a pro-rated basis up through final visit completed.

**Inclusive of all study-related training, investigator meeting, initiation meetings, progress notes, EDC training, electronic EDC signatures, confirming Inclusion/Exclusion, and AE/SAE Assessments, provide full oversight to the study team, etc.

Patient Stipend @ 11 visits	\$550
Total Per Patient Stipend (Paid Directly by Site)	\$5,500

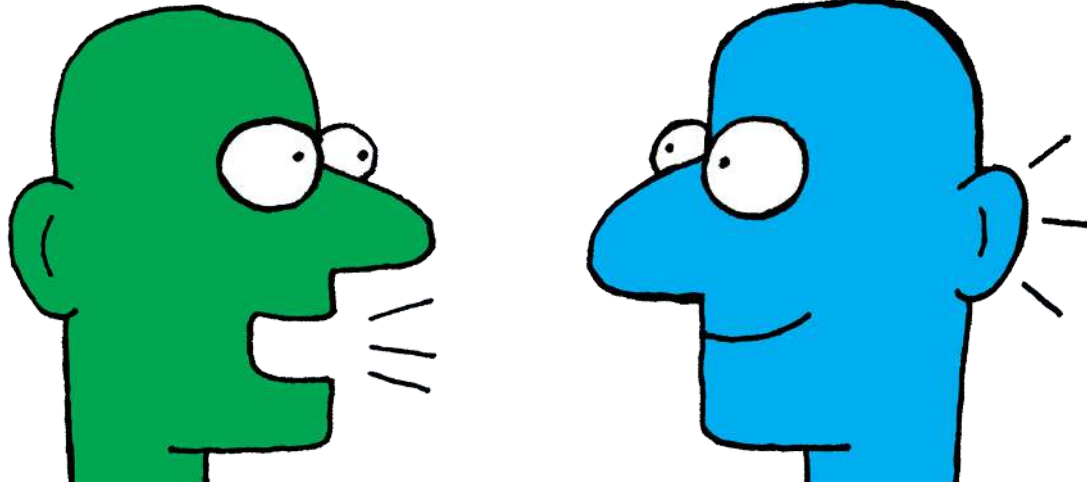
Non-Competition Agreements

- Very important to protect your IP
 - You will be opening your “book” of business and company model
 - Showing them your relationships
 - If the P.I. is currently not conducting research, we recommend including a non-competition agreement
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Non-Competition Agreements

- What to include:
 - Non-Competition Agreement: Upon termination of this Agreement for any reason and for a period of two (2) years thereafter, Investigator and xxx, agrees that they shall not, directly or indirectly, engage or participate in any studies with any research company and/or sponsor. In addition, disclose to any person, firm or corporation the names or addresses of any companies with whom Investigator and xxx have had business contracts or business relationships, except as required by law or pursuant to an order by a court of competent jurisdiction. The “Investigator” agrees that a violation of this section by Investigator shall entitle xxx to receive, jointly severally from Investigator, liquidated damages equal to 60% of the gross amount (before deducting any business costs or expenses) earned by Investigator. The parties agree that the liquidated damages set forth above shall serve as reasonable compensation to xxx for the damage caused to it by a breach of this section, it being understood that actual damages would be difficult if not impossible to quantify.

Best Practices for Budget Negotiation and Allocation



Profit margins are decreasing, so verify your budget is fair and reasonable!

- Ensure proper reimbursement per the time associated with your protocol
- Always do your due diligence when “pricing up” the budget
- Build relationships!
- Think big picture (total subject budget) instead of always worrying about each line item.

Don't Start the Job Without Your Tools!

- Always obtain the full study protocol, including the time and events table
- Make sure to clarify the use of vendors and supply reimbursement
 - Are all lab supplies being supplied?
 - Is there a central lab?
 - Is there any equipment needed that we don't have?

Building Your Budget

- If the sponsor provided the budget on a per visit basis, first request an itemized budget showing the procedural costs.
 - *Always try and obtain their proposed amounts first, don't negotiate against yourself.*

- If not provided, price up the budget using the **procedural cost spreadsheet (see later)**

- Start high for each procedure, end where you want!
 - Include your P.I. Fee and CRC Fee!
 - Include your OH amounts and any Patient Stipends

Fees & Start-up Costs

- Make sure to include all additional fees
 - Start-up fees – non-refundable and refundable
 - Prescreen log reimbursement
 - Rater training
 - Pharmacy fees
 - Archiving fees
 - S/F ratios
 - Advertising
 - SAE fees
 - Unscheduled visit fees
 - Audit fees
 - Monitor change fees
 - Re-consent fees
 - Amendment fees
 - Data mining
 - Chart review
 - IND safety reports
 - Misc expenses i.e. supplies, dry ice, etc.

Screen Failures

- Always provide reasons or examples for your requests
- Request the total amount of the actual visit
- Make sure to confirm timing of baseline visit (Visit 2 or later) and add visit amounts depending on which visit the actual SF occurs
- Re-negotiate after the start of the study if the SF ratio is “upside-down”
 - Examples of SF reimbursement: Ratio (R:SF) , SF Cap (10 reimbursable SF’s), SF cap then a ratio thereafter, per procedure completed.

Other Pass Through Fees and Diagnostic Tests *forte* Research Systems[®]

- Apply your OH rate to all fees and Dx expenses
 - *with a little extra for management time*
 - Pull Diagnostic Tests out of the per subject budget and request reimbursement for all as a pass through
 - *too much exposure if a “non-reimbursable SF”*
 - Dry ice, extended subject travel reimbursement, meals, IRB fees, medical records fee, printing costs, teleconference attendance, etc.
-

What Should I ask for?

Ambulatory BP Measurement	\$120	\$75
Blood Alcohol Test	\$23	
Blood Collection for Biomarkers	\$65	\$45
Blood Collection for PK Analysis	\$75	\$40
Blood for APOE Genotype/Pharmacogenomics	\$75	\$50
Breath Alcohol Test	\$45	
Chest Radiograph	\$200	
CT Scan	\$2,500	
Electrocardiogram (ECG)	\$150	\$100
Electrocardiogram (ECG) 12 Lead - Single	\$175	
Electrocardiogram (ECG) 12 Lead -Triple	\$200	\$110
Genetic DNA Evaluations	\$50	
GU Exam	\$200	
Hormone Tests	\$25	
Intravenous Infusion Fee	\$135	
Labs & Urinalysis	\$150	\$70
MRI	\$3,500	\$2,000
Neurological Exam	\$275	
Neurological Exam - Abbreviated	\$175	
Nicotine and alcohol use	\$30	
Office BP measurement	\$60	\$45
Patient identification card dispensed	\$50	
Patient identification card returned	\$45	
Pelvic Examination /Pap	\$125	
Pharmacy Dispense Fee	\$80	
Pharmacokinetics & Immunogenicity	\$80	
Photographs of Skin Lesions	\$65	
Physical Examination	\$300	\$165
Physical Examination - Follow Up	\$175	
Physical Examination & Neurological Examination	\$350	\$300
PK & PD Sampling	\$150	\$125
Psychiatric History	\$95	
Rivastigmine/galantamine accountability tracked	\$75	
Serum Pregnancy Test	\$35	
Study Drug Administration	\$65	
Study Treatment Dispensed	\$125	\$75
Study Treatment Returned, Accountability tracked	\$75	
Telephone Call	\$75	\$65

Conclusions

- **Be fair, honest, and nice!**
 - **Know your protocol and maximize the budget and CTA language accordingly**
 - **Know when to pass**
 - **Review the SF reimbursement**
 - **Thoroughly review the CTA language and negotiate each component**
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Thank You



Contact:
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