

Scenario 2 – Clinical Trial Budget – “Splintz’R’Us” [Queen’s]

You and your study team have written a protocol for a clinical study. The study follows subjects who have suffered ligament damages that are either surgically repaired or treated with immobilisation and rehabilitation. It is observational but requires the collection and delivery of blood to your study team for analysis. The study should take six months.

The study allows for a maximum of 100 subjects at 10 sites in Canada.

- Your minimum administrative costs are \$5000 plus indirect costs of 30%

For the sites:

- Per case funding is \$500 per patient or a maximum of \$50,000.
- Each site requires a blood kit worth \$3000 each at full market value (or \$30K in total).
- Each site requires a \$5000 start-up cost to cover REB, coordinators etc.

The total amount for a successful trial at full cost ranges between \$135,000 and \$140,000.

A large medical supply company is very interested in the study and is willing to offer financial support. In return for the funding, you will grant them an option to any new invention or improvement related to their products. **The company has made an initial offer of \$120,000**

You have signed an NDA to discuss the timing and amount of funding required. In particular, you want to discuss:

- 1) Total budget including indirect costs
- 2) Timing of payments (initial study start up, site start up, per patient amounts)
- 3) Return of funds if the study is not successful

Principal Investigator - Study Team Member

- 1) **Indirect Costs** – The institution has agreed to waive indirect costs on the administrative fee down to 10% but would prefer you try for the full amount. If you argued, you might be able to get a full waiver.

Blood Kits – If you buy in bulk, you get a 50% discount reducing the total cost to \$15,000

Per Case Fees – As a favour, your colleagues have accepted these very low fees. You cannot go any lower.

Study Start Up - \$5000 is a reasonable rate. Some sites may accept slightly lower amounts but others will want higher amounts. You want to keep things consistent.

- 2) **Timing of Payments** - Five sites are fully committed. You will need to pay their start up fees quite quickly. Other sites will join more quickly if they are assured of payment. The sites will wait 45 days for per patient fees, invoiced monthly. You will need to pay \$15,000 for all the blood kits immediately to take advantage of the discount. **You do not want to run a deficit.**
- 3) **Return of Funds** – There is no refund for the blood kits if purchased at a discount. The sites want to keep their start-up fees even if no subjects are recruited.

Scenario 2 – Clinical Trial Budget – “Splintz’R’Us” [Company]

You and your study team have written a protocol for a clinical study. The study follows subjects who have suffered ligament damages that are either surgically repaired or treated with immobilisation and rehabilitation. It is observational but requires the collection and delivery of blood to your study team for analysis. The study should take six months if rolled out quickly.

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Company

- 1) **Total Costs** – Your Company is very interested in the results of this study. The Company knows that clinical studies are expensive and will entertain any reasonable offer. **However, as the negotiator you don’t want to be pushed around and want to be able to show your boss you are frugal with the company’s money.**

Indirect Costs – The Company has heard other institutions do not charge overhead. Why do we need it here? You would prefer an all-inclusive figure instead of added overhead.

- 2) **Timing of Payments** – The Company is able to pay the entire amount up front but sees no reason to do so. It also wants to be sure payments match milestones. There is a chance the company may be taken over so **they do not want payment timing to be too complicated.** Better if the schedule has clear payment dates. The company has a 30-day turnaround for invoices.
- 3) **Return of Funds** – The Company has had trouble in the past with studies that went nowhere after large amounts of money were paid. You want something to show for the funds. Maybe if there are clear progress reports, your boss would be happier approving funding.
- 4) **Return of Funds** – There is no refund for the blood kits if purchased at a discount. The sites want to keep their start-up fees even if no subjects are recruited.