

# Research Study Budgets



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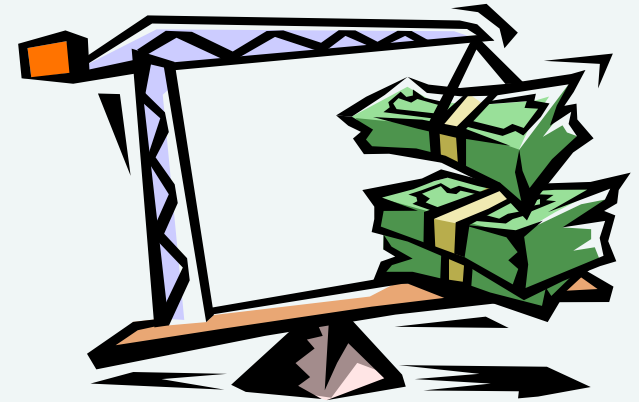
**Workshop**

February 7<sup>th</sup>, 2013

*A different today. A better tomorrow.*

# Overview

1. Budget requirements
2. Creating the study budget
  - Steps in the process
  - Per patient fee schedule
  - Additional expenses
  - Calculating overhead
3. Negotiating your budget
4. Prepare a study budget



# Budget Requirements

The study budget must cover all study related costs

- ✓ Staffing
- ✓ Space
- ✓ Supplies
- ✓ Services from other departments
- ✓ Institutional costs

# Responsibilities

The Investigator is ultimately responsible should a study account go into deficit

- Each study needs a line-item budget
- Investigator initials budget in the contract
- Investigator must find additional funds to cover outstanding costs

An industry sponsor has invited you to participate in an upcoming clinical trial!

You have consulted Research Services and have a confidentiality agreement in place.

*Activity #1: Put the 10 steps of budget development and implementation in order.*

# Study Budget Steps

1. Review protocol and budget from sponsor
2. Assess whether the study is feasible
3. List procedures and request price estimates
4. Set start-up fee & operating expenses; prepare per patient fee schedule (line item budget)
5. Review line item budget & invoiceables with RS
6. With RS, negotiate CTA with sponsor
7. Finalize budget, get Investigator's final approval
8. Execute Research Services' approved CTA
9. Arrange department service agreements
10. Request amendments to the budget if necessary

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# Review your Protocol

- Consider your patient pool
- Feasibility with CH services/resources
- What will it cost to run the study?

# Consider your Patient Pool

- ☐ Inclusion/exclusion criteria
- ☐ Size of pool
- ☐ Process of identification & recruitment
- ☐ Recruitment rate
- ☐ Rate of withdrawal
- ☐ Compliance
- ☐ Location (travel expenses)



# Services & Resources are Limited

- Contact required departments
- Provide as much information as possible
- Surgery requires pre-approval (6-8 weeks)
- Echocardiograms require pre-approval
- Radiology procedures for research may be limited in number and scheduling allotments

# Study Expenses

## Line-item budget:

Per patient fee schedule with all procedures and staffing listed for each visit

- Request from sponsor
- If not provided an internal line-item budget must be developed (but takes time)
  - Derived from protocol (assessment schedule)
- Know your protocol, itemize **everything**

# Most often receive...

Visit type	Description	Cost
Screening & Baseline	Assessments	645
Treatment	Visit 1 (Day 1): inpatient visit	296
Treatment	Visit 2 (Day 7): Inpatient visit	329
Treatment	Visit 3 (Day 14): Discharge visit	508
End of study	End of study visit (Day 30)	476
Follow-up	Phone call (6 months)	98
	Per patient total	2352
***NOT A LINE ITEM BUDGET ***		

Per visit  
totals

Overhead  
inclusive

Procedure	Baseline & Screening	Visit 1 (Day 1)	Visit 2 (Day 7)	Visit 3 (Day 14)	End of Study Visit (Day 30)	Follow-up Visit (6 m) phone call
Physical exam	160			160	160	
Med history	80					
Blood draw	56	56	56	56	56	
Consent	85					
I/E Criteria	50					
Randomization	15					
Dispense drug		22	22			
Ship to lab		75	75	75	75	
Compliance			25	25		
AE assessment		25	25	25	25	25
Complete CRF	50	50	50	50	50	50
Visit total	496	228	253	391	366	75
Total per patient		1809	What other items could be listed in this line item budget?			
Total Overhead		543				
Total per patient with OH		2352				

# List all activities and procedures:

- Informed consent
- Medical history
- Physical exam
- Medical procedures
- Blood draws
- Shipments to lab
- Sample processing /packaging, dry ice
- Surveys
- Sub-study:
  - Consent
  - Procedures
- Phone-calls
- Subject reimbursement

# Coordinator time

List activities separately or combine under study maintenance

- Common tasks: AE assessment, CRF/eCRF completion, drug compliance, concurrent medication assessment
- Also consider: recruitment, monitoring visits, queries, correspondence, etc... that might not be included in the budget

# Input fees per item

- Fee for each procedure/activity by visit
- Consider your patient pool:
  - Estimate time for each procedure
  - Patient reimbursement for travel
    - Local (per visit) or if >100km (travel allowance)
  - Screen failure rate, compliance, withdrawal
- Consult Investigator & other Coordinators
- Get estimates from service departments

# Services from other departments

For a good estimate:

- Supply all information materials:
  - Protocol & brochure
  - Manuals & special instructions
- Provide sponsor's contact information
- Get an up-to-date quote

\*If service is not provided at CH consult  
Procurement to outsource



# Input Procedural Expenses

- Estimate time for medical history, informed consent, adverse events, file maintenance...
- Standard fees:
  - Coordinator time (~\$55-60/h)
  - Investigator time (~\$150/h)
- Input estimates from service providers (remember start-up & other fees)
- Add lab fees if visit specific

# Institutional Overhead

*30% overhead applies to all budget expenses*

There are **three** overhead exempt items:

1. REB initial review is \$3500
2. Record retention:
  - \$1000 for Phase I-III studies (25 years)
  - \$500 for Phase IV/observational studies (7 years)
3. Site start-up fee (goes to research account):
  - \$5000-7500 for Phase I-III studies
  - \$2500-5000 Phase IV/observational studies

# Extra costs (invoiceable items list)

- Advertising
- Protocol amendments
  - Major (ICF changes)
  - Minor
- REB documents
  - Quarterly safety reports
  - Annual renewals
  - Close-out
- IND safety report processing
- SAE reporting
- On-call (\$30/day+OH)
- Initiation & close-out visits
- Audits (HC, FDA, CH,...)
- Extra patient travel expenses (>100 km)
- Other departments:
  - Pharmacy, Lab & Radiology start-up fees
  - Dry ice shipments
  - Pharmacy drug maintenance, audits, monitoring & on-call
  - Radiology data CDs
  - Biomedical engineering

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# Calculating overhead

Inclusive fees are those that have the 30% overhead included:

$$\begin{aligned}\text{Inclusive fee} &= \text{actual fee} + \text{overhead} \\ &= 1.3 \times \text{actual fee}\end{aligned}$$

$$\text{Actual fee} = \text{Inclusive fee} \div 1.3$$

$$\begin{aligned}\text{Overhead} &= (1 - 1/1.3) \times \text{Inclusive fee} \\ &= 0.231 \times \text{Inclusive fee}\end{aligned}$$

# Calculating Overhead



## Activity #2

Visit type	Description	Inclusive	Actual	Overhead
Screening & Baseline	Assessments	645		
Treatment	Visit 1 (Day 1): inpatient visit	296		
Treatment	Visit 2 (Day 7): Inpatient visit	329		
Treatment	Visit 3 (Day 14): Discharge visit	508		
End of study	End of study visit (Day 30)	476		
Follow-up	Phone call (6 months)	98		
	Per patient total	2352		

# Answers

Visit type	Description	Inclusive	Actual	Overhead
Screening & Baseline	Assessments	645	<b>496</b>	<b>137</b>
Treatment	Visit 1 (Day 1): inpatient visit	296	<b>228</b>	<b>63</b>
Treatment	Visit 2 (Day 7): Inpatient visit	329	<b>253</b>	<b>76</b>
Treatment	Visit 3 (Day 14): Discharge visit	508	<b>391</b>	<b>117</b>
End of study	End of study visit (Day 30)	476	<b>366</b>	<b>110</b>
Follow-up	Phone call (6 months)	98	<b>75</b>	<b>23</b>
	Per patient total	2352	<b>1809</b>	<b>543</b>

\*Sums may not be equal due to rounding

Procedure	Baseline & Screening	Visit 1 (Day 1)	Visit 2 (Day 7)	Visit 3 (Day 14)	End of Study Visit (Day 30)	Follow-up Visit (6 m) phone call
Physical	160			160	160	
Med History	80					
Blood draw	56	56	56	56	56	
Consent	85					
I/E Criteria	50					
Randomization	15					
Dispense		22	22			
Ship to lab		75	75	75	75	
Compliance			25	25		
AE assessment		25	25	25	25	25
Complete CRF	50	50	50	50	50	50
Visit total	<b>496</b>	<b>228</b>	<b>253</b>	<b>391</b>	<b>366</b>	<b>75</b>
Total per patient		<b>1809</b>				
Total Overhead		<b>543</b>				
Total per patient with OH		2352				

# Negotiating your budget

- Back and forth, Research Services (ME!) can facilitate this process
- Can take months...
  - What is your time limit?
  - When will you prepare your REB submission?
  - What if the contract is cancelled?
  - Do you have an inside contact with the sponsor?



# Questions?



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# Exercise:

## Prepare a study budget

First...Coffee break!



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# Coordinator Budget Tools

Coordinator budget tools:

1. Budget checklist
2. Research contact list
3. Templates:
  - I. Site start-up fee breakdown
  - II. Site operating expenses
  - III. Excel line-item budget



# Consider...

- Patient pool
  - Recruitment rate
  - Screen failures (inclusion/exclusion criteria)
  - Withdrawal & compliance rates
- Other sponsor driven expenses
  - Monitoring rate (i.e. site, pharmacy, radiology)
  - Required training (i.e. eCRFs, GCP)
  - Administration (i.e. Form 1572)
  - Data entry (i.e. eCRFs)



# 1. Site Operating Expenses

1. What is your requested site start-up fee?
  - a) Justify your site start-up fee for Protocol SAD-INT-63001
  - b) How will it be distributed?
2. What other operating expenses do you anticipate?
  - a) Set your operating expenses for Protocol SAD-INT-63001
  - b) How will you bill?

## NON-REFUNDABLE SITE START-UP FEE

<b>1. PROTOCOL REVIEW .....</b>	<b>1000</b>
Investigator .....	700
Research Coordinator .....	300
<b>2. ETHICS APPLICATION .....</b>	<b>1500</b>
Ethics submission form, questionnaires, support letters .....	1000
Informed consent form(s) .....	300
Departmental service agreements .....	200
<b>3. ADMINISTRATION .....</b>	<b>2000</b>
Office supplies, space, phone, internet .....	500
Regulatory package .....	1000
• FDA 1572 (if applicable), TPD QIU, and CTSI	
• Financial disclosure forms	
• Physician CVs & medical licenses	
• Research Coordinator CVs & applicable licenses (RNANS, Pdt, etc.)	
• Hospital accreditation	
• Laboratory normal ranges	
• REB members list	
• Delegation log	
• Notes to file	
• All other requests by Sponsor/CRO	
File maintenance for duration of study .....	500
• Correspondence with Sponsor, CRO, REB, Health Canada, CDHA service departments	
<b>4. RECRUITMENT ACTIVITIES .....</b>	<b>500</b>
Sub-Investigator recruitment presentations .....	500
<b>5. TRAINING .....</b>	<b>1000</b>
Investigator & Sub-Investigators .....	700
Research Coordinator and Research Assistants .....	300
<b>TOTAL SITE START-UP FEE .....</b>	<b>6000</b>

SERVICE	Set Fee
<b>Initial REB submission</b> (invoiced, OH exempt)	3500
<b>Record retention</b> (invoiced, OH exempt)	1000
<b>Site preparation</b> (invoiced, OH exempt) <ul style="list-style-type: none"> <li>• fee breakdown available upon request</li> </ul>	6000
<b>Investigator's meeting</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• travel-related expenses</li> </ul>	Invoiced +OH
<b>Site initiation visit</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• Set fee</li> </ul>	350+OH per visit
<b>Site close-out visit</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• Minimum payment for one hour</li> </ul>	350+OH per visit
<b>Site audit</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• Sponsor/CRO/Health Canada/FDA/Institutional</li> </ul>	350+OH per audit
<b>Pharmacy</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• Site pharmacy: start-up, quarterly maintenance, close-out, dispensing</li> </ul>	500+OH start-up 500+OH maintenance 300+OH close-out 20 per dispensing
<b>Lab Shared Services start-up fee</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>• processing</li> <li>• packaging</li> <li>• dry ice</li> </ul>	150+OH start-up 15+OH 25+OH 75+OH/shipment
<b>Advertising</b> (invoiced, inclusive of 30% OH)	2000, unused portion from invoices will be returned

<b>Major protocol amendment</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>include changes to ICF, re-consenting</li> </ul>	750+OH
<b>Minor protocol amendment</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>no ICF changes</li> </ul>	500+OH
<b>Annual renewal</b> (invoiced, add 30% OH)	500+OH
<b>Study close-out report</b> (invoiced, add 30% OH)	500+OH
<b>Processing IND safety reports</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>sent for physicians review and signature and filed in ISF</li> </ul>	25+OH/report
<b>SAE reporting</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>includes adjudicated AEs</li> </ul>	300+OH/patient event
<b>Screen failures</b> (invoiced, add 30% OH) <ul style="list-style-type: none"> <li>check limit suits inclusion/exclusion stringency</li> </ul>	As per work done on the screening visit
<b>Unscheduled Visits</b> (invoiced, add of 30% OH)	200+OH + as per work completed
<b>Patient reimbursement</b> (invoiced, add of 30% OH) <ul style="list-style-type: none"> <li>travel-related expenses</li> <li>extenuating travel invoiced separately (memo with explanation available)</li> </ul>	45+OH/visit Invoiced separately, subject to OH



## 2. Line-item Budget

Create a line-item budget using Protocol SAD-INT-63001

1. Will you need any other department services?
2. How much more per visit would you request?
  - a) What will you settle for?
  - b) Is the Investigator willing to walk away?

Per patient costs (overhead applied):													
Visit	#	Fee	Screening	1	2	3	4	5	6	7	8	9	
Informed Consent	1	150	150										
Pregnancy Test	1		30										
History and Physical Exam	2	50	50										
Height & Weight	13	20	20		20	20	20	20	20	20	20	20	
Blood pressure	13	20	20		20	20	20	20	20	20	20	20	
Baseline Medications	1		20										
Investigator DSM IV assessment	1	150	150										
EKG	2	56	56										
Blood draw	8	25	25		25		25		25		25		
Lab Processing, Shipping & Dry Ice	8	75	75		75		75		75		75		
Suicidal Risk	13	20	20		20	20	20	20	20	20	20	20	
Calgary Depression Scale	13	55		55	55	55	55	55	55	55	55	55	
Inclusion/Exclusion Criteria	1	55		55									
Randomization	1	30		30									
Medication Dispensing	13	22		22	22	22	22	22	22	22	22	22	
Compliance	12					20	20	20	20	20	20	20	
Concomitant meds	12				20	20	20	20	20	20	20	20	
Adverse Events	12				20	20	20	20	20	20	20	20	
Off study treatment	1	150											
Coordinator's time	7.5	55	30	30	30	30	30	30	30	30	30	30	
Patient reimbursement	14	15	15	15	15	15	15	15	15	15	15	15	
Total per visit			661	207	322	242	342	242	342	242	342	242	
Overhead per patient 30%			198.3	62.1	96.6	72.6	102.6	72.6	102.6	72.6	102.6	72.6	
Total with overhead			859.3	269.1	418.6	314.6	444.6	314.6	444.6	314.6	444.6	314.6	

## Based on your line-item budget...

3. Would you request more for a phase II study?
4. How many patients do you need to recruit to cover one month of Coordinator's salary?

# Coordinator's Salary

1. ***Calculate salary:*** Salary equals hours worked per week times hourly rate including benefits times number of weeks in 1 month
2. ***Calculate per patient amount:*** Coordinator & Investigator fees for visits up to one month (not patient reimbursement or dept fees)
3. ***Calculate number required to recruit:*** Divide salary by patient amount, always round up

# Number to Recruit to Cover Salary

1. Coordinator's salary for one month

$$= \$55/\text{h} \times 37.5\text{h}/\text{wk} \times (52\text{wk} \div 12\text{mo} \times 1\text{mo})\text{wk}$$

$$= \$8937 \text{ for one month}$$

2. Coordinator amount per patient for one month

$$= \$515 + \$192 + \$232 + \$227 + \$252 + \$227$$

$$= \$1645 \text{ per patient}$$

3. Number of recruited patients required

$$= \$8937 \div \$1645$$

$$= \mathbf{6 \text{ patients}}$$

## 3. Invoiceables

List all extra anticipated costs to be billed by invoice for Protocol SAD-INT-63001

1. What items would you list?
2. Which are most important?
3. What would you be willing to settle for?

One time fees overhead exempt (invoiceable)	
REB fee	3500
Record retention	1000
Site start up fee	6000
<b>Total one time fees</b>	<b>10500</b>

Pharmacy start-up can be for research team (temperature log, space) or pharmacy department (with additional fees) as required

Start up fees overhead inclusive (invoiceable)	
Advertising	2000
Pharmacy start up fee	650
Lab shared services start up fee	195
<b>Total one time fees subject to overhead</b>	<b>2845</b>

Remember to allocate 30% for overhead on all invoices.

Jane MacLeod in Research Finance can provide and submit invoices on your behalf.

Extra fees overhead inclusive (invoiceable)	
REB annual renewal	650
Protocol amendments (per amendment)	650
Major amendments (ICF changes, re-consenting)	975
Pharmacy maintenance (yearly)	650
Pharmacy close-out	390
Site audits	350
Extraordinary travel expenses (>100km)	<350
Safety reports or IND reporting (per report)	33
Biomedical engineering (per hour)	128

# Negotiate budget

Cross reference with proposed budget

## 1. Discuss with Research Services

- Identify additional fees
- RS can moderate negotiations
- RS needs to ensure institutional costs are covered

## 2. List all additional requests

## 3. Correspond with sponsor

## 4. Finalize, review, approve (Investigator & CH)

## 5. Execute contract, get REB approval

## 6. Begin enrolment, amend contract as necessary

*A different today. A better tomorrow.*



# Thank you!

## Questions?

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## Further Questions or Requests for Assistance

Resources available at Research Services website:

<http://www.cdha.nshealth.ca/discovery-innovation-10>

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