

Budgets & Finance



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Simon Wong

Creating Budgets

Tips and Tools

Budgeting

budget_template_2014 [Compatibility Mode] - Excel

Simon Wong

B1

Part A: Per Subject Costs				
	# of Subjects	Unit Cost	Sub Total	
Per Subject Cost	10	\$ 8,360.30	\$ 83,603.00	
Subject Honoraria & Parking	10	\$ 880.00	\$ 8,800.00	
Sub Total			\$ 92,403.00	

Part B: Study Costs				
	# of Encounters	# of Hours	\$/Hour	Sub Total
<i>Site Start Up</i>				
Feasibility Assessment	1	2	\$ 65.00	\$ 130.00
Protocol Review	1	8	\$ 65.00	\$ 520.00
Contract Preparation (includes legal fees)	1	3	\$ 250.00	\$ 750.00
Budget Preparation & Monitoring	1	12	\$ 65.00	\$ 780.00
HREB Submission Preparation	1	8	\$ 65.00	\$ 520.00
HREB Revisions: ICF, protocol clarifications, sponsor's approval of same	8	1	\$ 65.00	\$ 520.00
Regulatory Documents Preparation & Maintenance	1	8	\$ 65.00	\$ 520.00
Source Document Preparation & Assembly	1	8	\$ 65.00	\$ 520.00
<i>Supplier Start Up</i>				
Contracting Support Services (DI, Lab, Pharmacy, CIU etc) Costing & Operational Approval	4	10	\$ 65.00	\$ 260.00
Clinical Trials Laboratory Start-up Fee	1		\$ 350.00	\$ 350.00
Pharmacy Start-up Fee	1		\$ 600.00	\$ 600.00
<i>Sponsor Initiated Meetings (Research Team Time)</i>				
Site Visit by Sponsor	1	3	\$ 65.00	\$ 195.00
Site Initiation Visit (SIV) by Sponsor	1	8	\$ 65.00	\$ 520.00
Safety Calls - Study Coordinator	2	1	\$ 65.00	\$ 130.00
Safety Calls - Study PI	2	1	\$ 300.00	\$ 600.00
Remote Data Entry Training	3	4	\$ 65.00	\$ 780.00
Monitoring Visits	10	2	\$ 65.00	\$ 1,300.00
Close out Visit	1	2	\$ 65.00	\$ 130.00
<i>Study Management</i>				

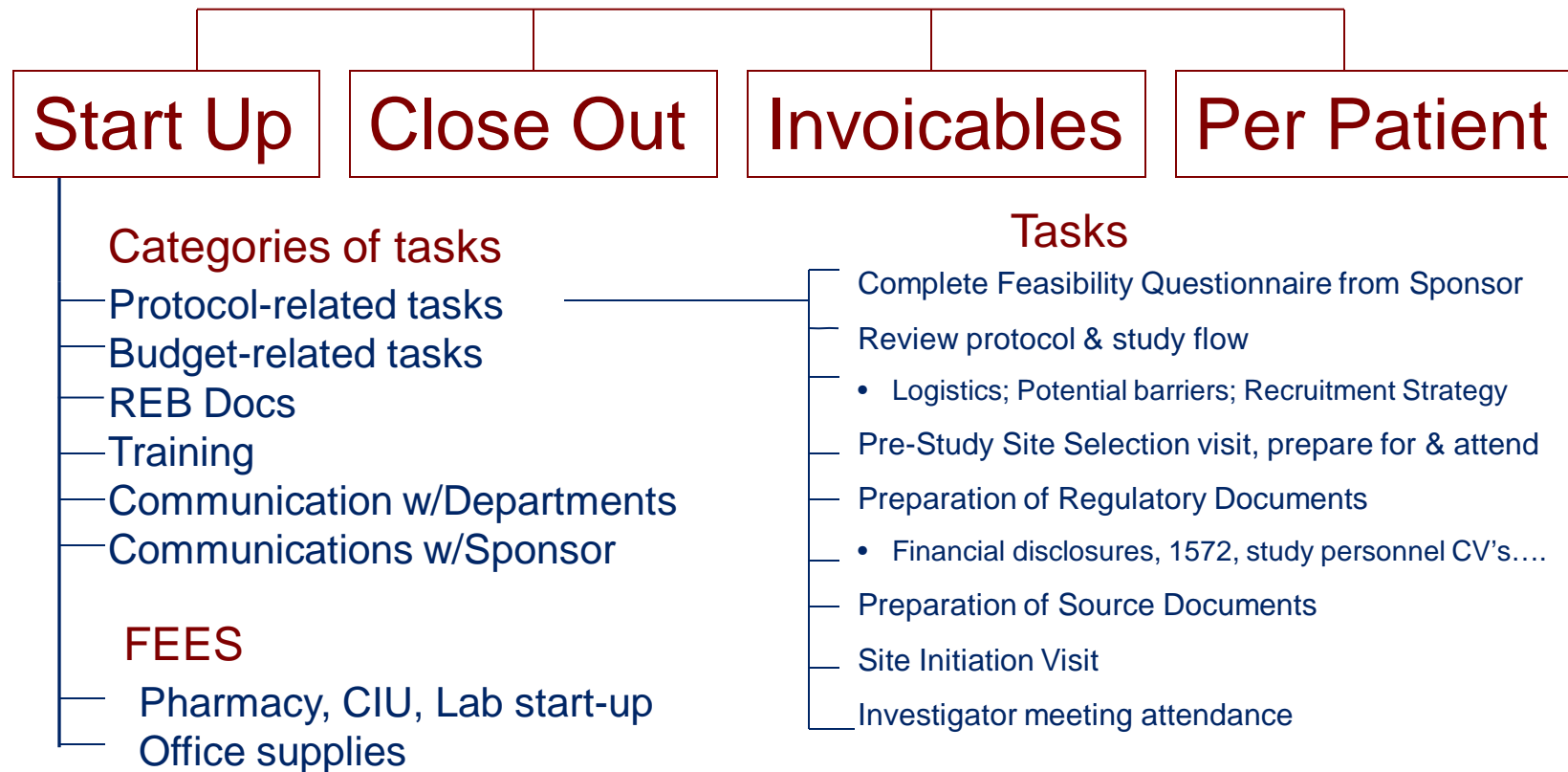
Page 1

Start Up Costs | Per Patient Costs | Invoiceable Costs | For C ...

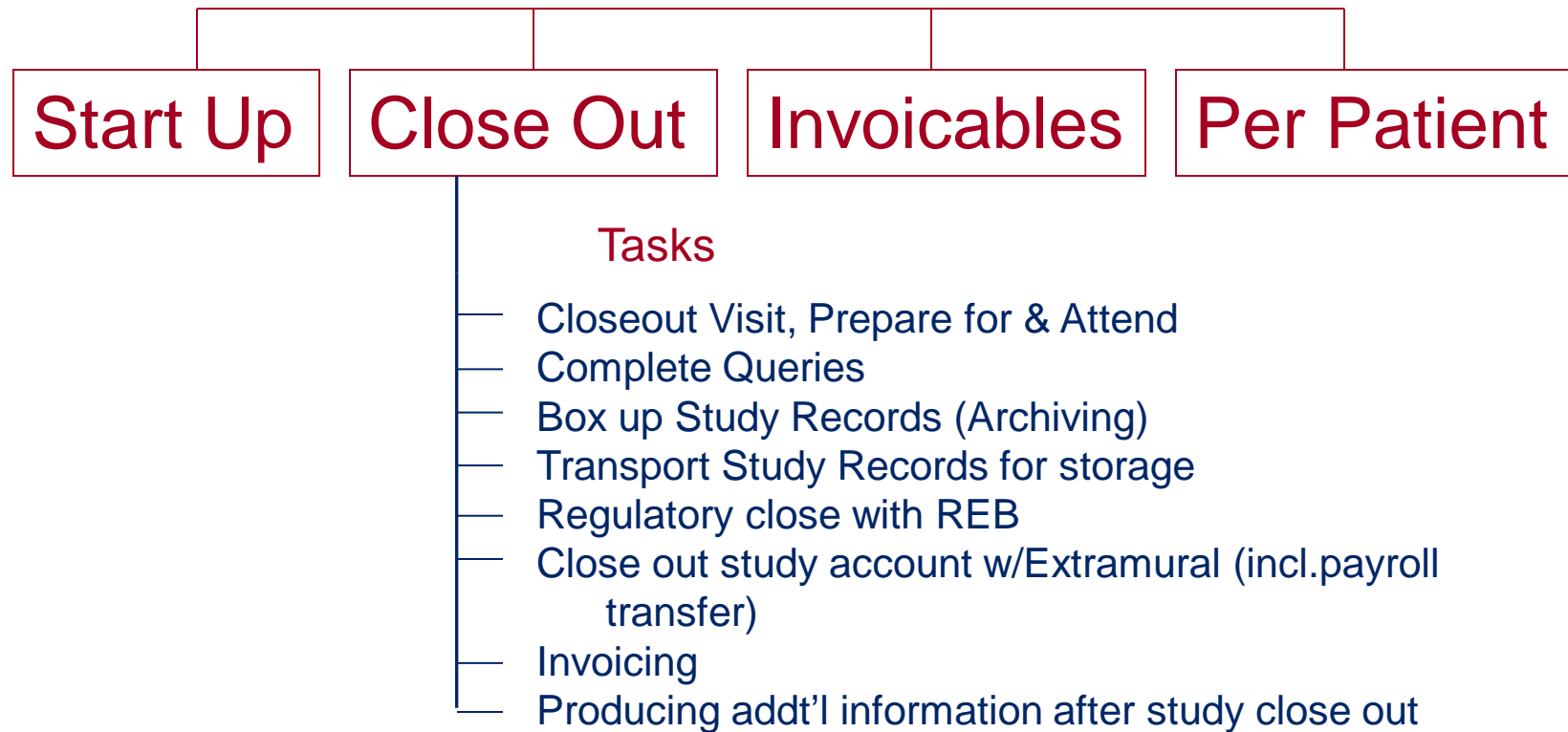
READY 75%

- Start-up
- Close-out
- Invoiceable
- Per-patient

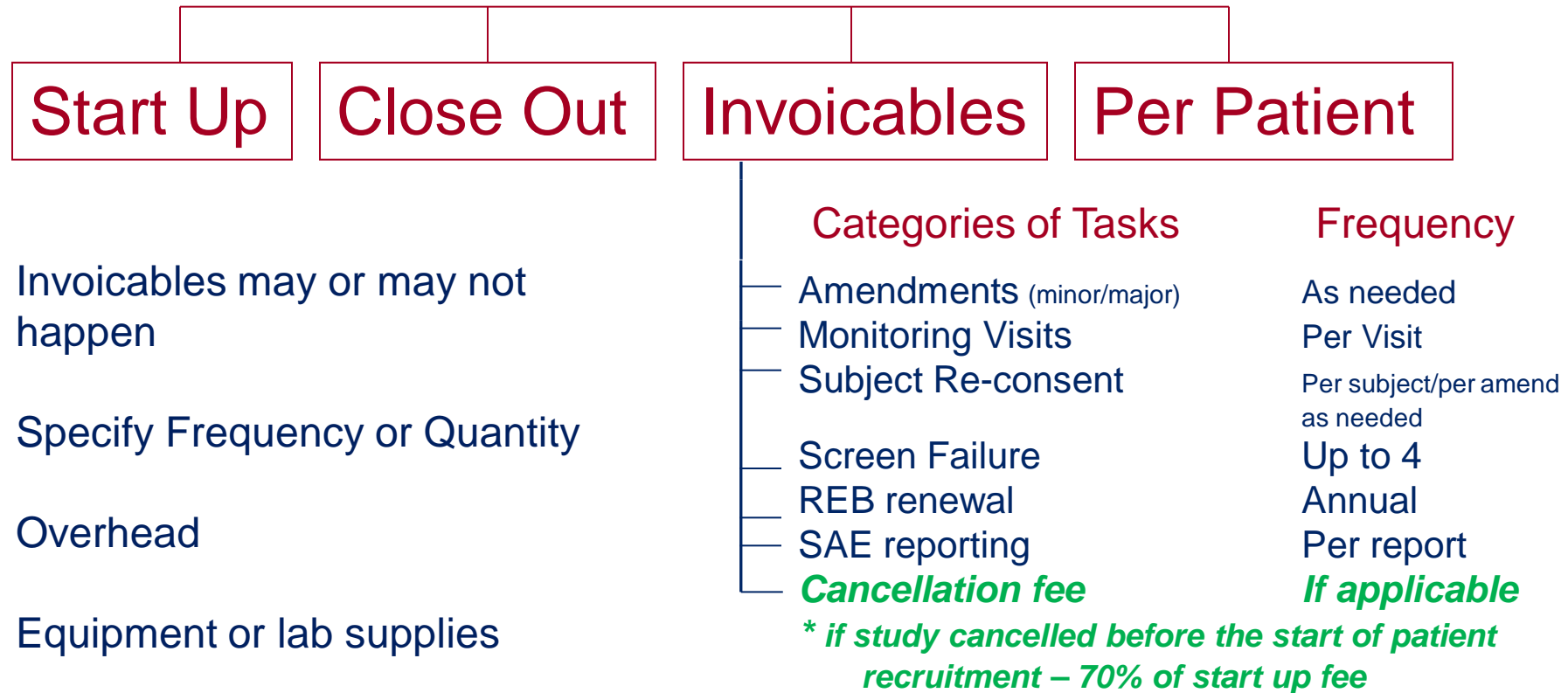
Start Up Costs



Close Out Costs



Invoicable Costs



Per Patient Costs



Schedule of Study Assessments *

Procedure	Screening ≤ 28 days from Baseline (First day of drug administration)	Cycle 1,2				Cycles 3,4,5,6		Discontinuation From Protocol Therapy	Follow- Up Phase Every 6 months
		Day 1	Day 8	Day 15	Day 22	Day 1	Day 14		
Informed Consent	X								
Record prior medications, treatments	X								
History, physical examination, vital signs, weight	X	X ^d				X	X	X	
ECOG performance status	X	X ^d				X	X	X	
Chest x-ray ¹ , Urinalysis	X								
ECG	X							X	
Hematology	X	X ^d		X		X	X	X	
Serum chemistry, LFTs ⁴	X	X ^d		X		X ^a	X ^a	X	
Pregnancy testing ⁵	X ⁶	X	X	X	X	X ^b	X ^b	X ^b	

Factors impacting budgets

- The type, phase, and complexity of the protocols involved
- Screen failure rates
- **The actual time it takes to perform the work**
 - Staff time/salaries
- Anticipated challenges
 - **Recruitment**
 - Patient demographics and scheduling challenges
 - Data management in busy studies
 - **Resources** – knowing what's available and how to access them

Budgeting Templates

Resources

NACTRC On-Line Application www.nactrc.ca

Get Started Protocol Bank My Requests **PI Resources** Contacts

PI Resources

AHS PRICING INFORMATION: STRICTLY CONFIDENTIAL
[Read More >>](#)

ARCHIVING CLINICAL TRIAL STUDY DOCUMENTS
NACTRC is pleased to announce that we have developed a process to assist investigators with archiving of clinical research documents. In collaboration with Alberta Health Services and Iron Mountain, the research community will receive the best available group rates for the storage and auto-destruction of these documents starting July 02, 2015.
[Read More >>](#)

CLINICAL TRIAL BUDGETS
While NACTRC is responsible for the legal aspects of your clinical trial contracts, the budget development and negotiations have always been left up to the PI. It is important to realize that study budgets can most often be negotiated between your site and the study sponsor but many sites do not take into consideration some of the expenses that they will incur in conducting the trial.
[Read More >>](#)

DSMB ASSISTANCE
DSMBs may be required for Investigator-Initiated trials sponsored by the University of Alberta that are determined to be high-risk after a protocol risk assessment has been completed. NACTRC will assist Investigators in setting up their DSMB, if required.
[Read More >>](#)

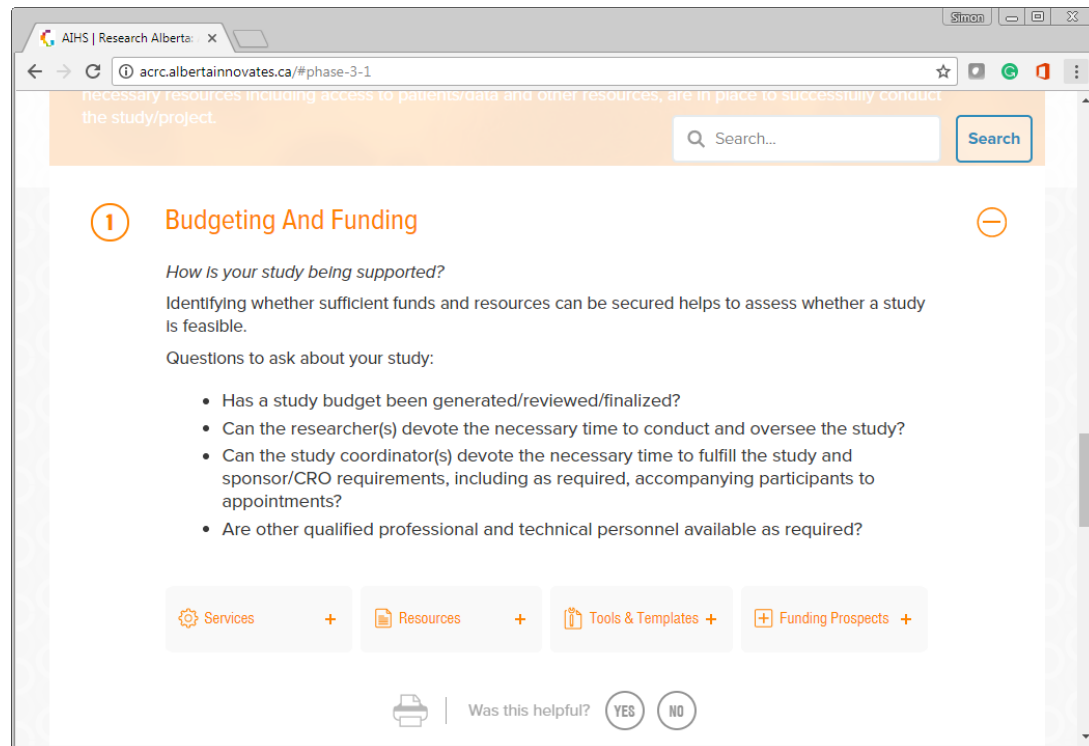
HEALTH CANADA CLINICAL TRIAL APPLICATION (CTA)
Some Investigator-Initiated clinical trials require the filing of a Clinical Trial Application (CTA) to Health Canada. A CTA must be filed **prior** to the initiation of a clinical trial in Canada.
[Read More >>](#)

INSTITUTIONAL OVERHEAD POLICY
All clinical trials administered by NACTRC on behalf of Alberta Health Services and The Governors of the University of Alberta are subject to institutional overhead. [Download the Policy](#)

PI Resources:

- AHS Pricing Information
- Budget checklist
- Budget templates

Alberta Clinical Research Consortium



<http://acrc.albertainnovates.ca>

- ACRC Internal Costing Guide
- ACRC Internal Costing Template

Negotiations

Tips and Tools

Budget negotiations...

- Sponsor's initial budget is STARTING POINT for negotiations (perform a thorough analysis of the specific protocol)
- Communicate resources available to conduct trial
 - Expertise
 - Facilities
 - Access to large patient population
- Remain neutral...establish that you are negotiating the budget on behalf of the study team
- A break-even point and bottom line should be determined

Budget negotiations...

- Keep the PI in your corner
 - Keep them informed
 - Ready to intervene
 - Ready to remind sponsor of the benefits of having you as a site
- Keep momentum going if negotiations are moving quickly
- Remain calm and exercise some patience
- Reach out to resources within the NACTRC for advice or assistance

Justification

- Sponsors are looking for justification of internal costs
 - Break it down for them

Major Amendment:

- *Discussions/correspondence between sponsor and site re changes to protocol and ICF (SC/PI's time)*
- *Amending ICFs (approval from sponsor – SC time)*
- *Ethics Submission*
- *Training (site personnel will need to attend 1 hr training session; 3 SC x 112/hr and 1PI/2 Sub-I's at \$350/hr)*

When to accept or walk away...

- Accept
 - Study objective is very important
 - Question needs to be answered
 - Grant – no room for negotiating
- Walk away
 - Discuss with your PI
 - Potential for a deficit (small or large)
 - Sponsor is being unreasonable

Standardized Site Costs

on the horizon?

- Sponsors want a standardized cost list

Advantages:

- Decrease negotiation time
- Other Institutions are providing this; keeps us competitive

Disadvantage:

- Sponsors will use this a precedent no matter what the situation
 - complexity of the protocol
 - other factors that may play into higher costs

Electronic Funds Transfers

Requesting and obtaining payment

EFTs

For AHS accounts only:

1. Request for Banking Information (RBI) form
 - Sponsor requests AHS banking info
2. Account Information Form (AIF)
 - AHS sends encrypted email
3. Pay Advice
 - When Sponsor makes EFT payment

1. Request for Banking Info



REQUEST FOR RELEASE OF BANKING INFORMATION:

This request is to release Banking Information for Direct Deposit into Alberta Health Services bank accounts.

Date of Request:

Company Information:

Name:

Address:

Company Contact Information:

Name:

Fax:

Currency of Deposits:

2. Account Information Form

-----Original Message-----

From: [REDACTED]

Sent: Wednesday, August 02, 2017 3:04 PM

To: [REDACTED]

Subject: !Private Banking Information Encrypted - Dr. [REDACTED] Research Proj [REDACTED]

Hello [REDACTED]

Attached are the letter with our banking information & a letter of confirmation from our bank. To open this encrypted email, you have to sign in as per the instruction that comes with the encrypted email.

Due to Privacy and Fraud Prevention, these banking details should not be included on future emails and payment notifications.

Thank you,
Cash Handling

2. Account Information Form (cont.)



9th Floor, North Tower SSP
10030-107 Street
Edmonton, AB T5J 3E4 CA

August 2, 2017

[Redacted]

ATTN: [Redacted]
Email: [Redacted]

Please accept this letter as information regarding payment(s) due as noted below.

Banking Information:

AHS (Beneficiary) Banking Information	
Destination Bank/Intermediary Institution:	[Redacted]
Intermediary Swift Code:	[Redacted]
Intermediary ABA Routing Code:	[Redacted]
Beneficiary Account with Institution:	[Redacted]
Beneficiary Swift Code:	[Redacted]
Beneficiary Account Number:	[Redacted]
Beneficiary Name:	Alberta Health Services

Very important!

Payment Reference Information:

Please include Principal Investigator's name, AHS Project # (payee name), Protocol # & Invoice #, if any, when remitting Funds.

Principal Investigator's	AHS Project
[Redacted]	[Redacted]

Payment Application and Contact Information:

In order to apply payment to your account, we require all wire payment confirmation details to be sent via email to the following AHS contacts.

Name	Phone	Email:
Edmonton Accounts Receivable	780-735-0999	EdmontonAR@ahs.ca
NACTRC		NACTRC.Finance@albertahealthservices.ca

Payment must be made in US Dollars (USD); all fees associated with this wire transfer will be the responsibility of the Remitter.

3. Pay Advice

[REDACTED]

From: [REDACTED]
Sent: Thursday, August 03, 2017 1:26 PM
To: Edmonton Accounts Receivable; NACTRC Finance
Cc: Lani Ongcoy; Filoza Bandali; Ron Welch; [REDACTED]
Subject: Payment of invoices from [REDACTED]
Attachments: Payment1783E1930D2B1605 [REDACTED].pdf

To Whom It May Concern,
Please see attached the wire confirmation for payment of 2 invoices totaling \$17,056 for [REDACTED]. The invoices being paid are INSP-12May2017 and INSP-20Mar2017. These are related to Research Project [REDACTED] with PI Dr. [REDACTED].

Thank you,
[REDACTED]
Controller

[REDACTED]

3. Pay Advice (cont.)

Payment Details Report



Company: [REDACTED]
Requester: [REDACTED]
Run Date: [REDACTED]

International High Value (Wire)
Payment Category: UrgentWire

Status: Confirmed by Bank
Transaction Number: [REDACTED]

Template Name: Alberta Health Services
Template Code: Alberta Health Services

Debit Account Information

Debit Bank: [REDACTED]
Debit Account: [REDACTED]
Debit Account Name: [REDACTED]
Debit Currency: USD

Beneficiary Details

Beneficiary Name: Alberta Health Services
Beneficiary Address: [REDACTED]
Beneficiary City: Edmonton, AB T5J 3E4
Beneficiary Postal Code: [REDACTED]
Beneficiary Country: CA - Canada

Beneficiary Account: [REDACTED]
Beneficiary Bank ID: [REDACTED]
Beneficiary Email: [REDACTED]
Beneficiary Mobile Number: [REDACTED]

Payment Details

Credit Currency: USD
Trade ID: [REDACTED]
Credit Amount: 17,056.00
Debit Amount: 17,056.00
Purpose of Payment: [REDACTED]

Value Date: 08/03/2017

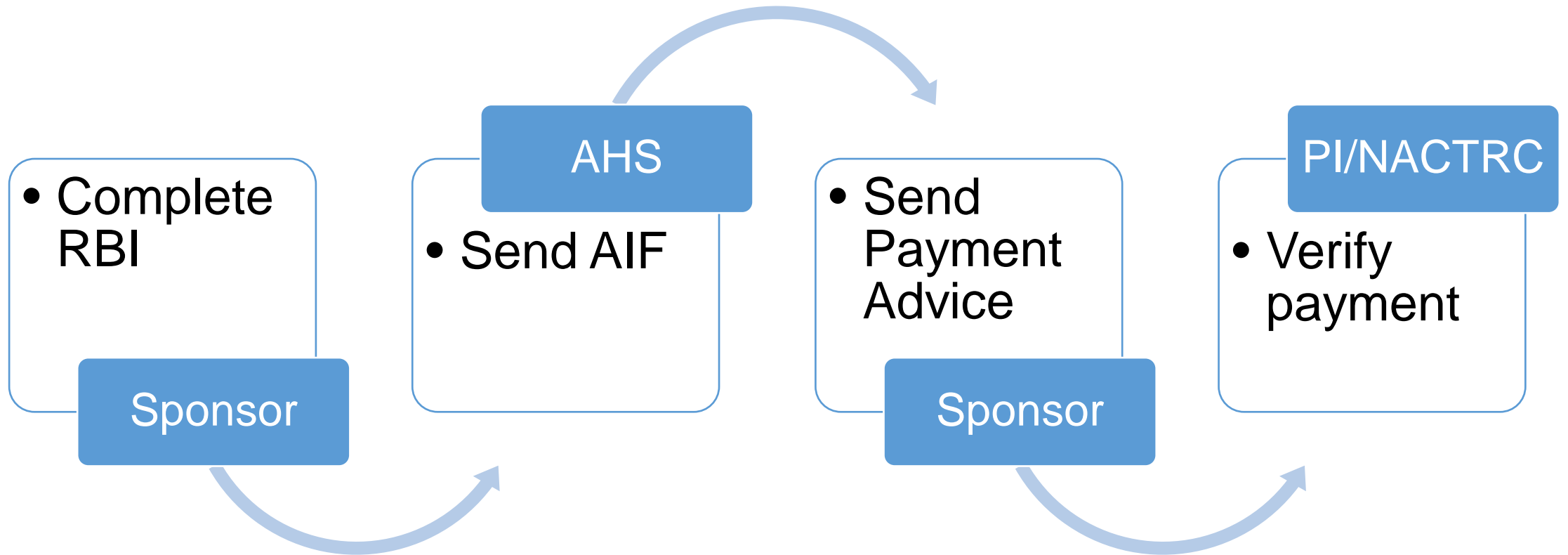
Optional Information

Sender's Reference Number: 1783E1930D2B1605

Beneficiary Information: [REDACTED] Inc.
PI - Dr. [REDACTED]
Proj number [REDACTED]
INSP-20Mar2017 and INSP-12May2017

Reference Info

Process Overview



New!

Emailing PI Reports (Exp. Jan 2018)

AHS Finance Investigator Report From April 1, 2017 to October 31, 2017

Note 1: <> = Positive Value

Note 2: This financial summary is provided to you by Alberta Health Services Finance and NACTRC to assist in your clinical trial management.

Please do not hesitate to contact Filoza Bandali at 780-735-0491 with any questions

Investigator:

Functional Centre	Beginning Balance April 1, 2017	YTD Revenue	YTD Expense	Ending Balance October 31, 2017
		0.00	0.00	
Total		0.00	0.00	

AHS Ledger

Research Reporting Detail Report

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Balancing : 103
Functional Centre : 71760000xxx
Site : 0300

AHS Externally Restricted Operating (DC)
xxx Salary Acct SFP
University Of Alberta Hospital

Mail id : 00xxx
GL Period : AUG-17

Account	Account Description	Amount	Line Description	Cur	GL Date	Vendor/Employee/Batch Name	Transaction# / Line#	Transaction Date
		1,000.00						
Closing Balance Total		1,000.00						
Surplus / Deficit for Period		1,000.00						