



Clinical Trials Quarterly

JULY 19, 2016

VOLUME 1, NUMBER 4

Lifespan Office of Research Administration

CLINICAL TRIALS CONTACTS:

Administrative Director:

Peggy McGill

pmcgill@lifespan.org

401-444-5113

Manager:

Deb Temple

dtemple@lifespan.org

401-444-6646

Clinical Trials Compliance

Administrator:

Gina L. Johnson

gjohnson@lifespan.org

401-444-4226

Senior Research Administrator:

Kim-Marie Lawrence

klawrence@lifespan.org

401-444-8554

The Internal Budget

The Clinical Trial internal budget form ("internal budget") is an MS Excel document designed to estimate the Institution's cost for participating in a clinical trial. This form is not meant to match the Sponsor budget, but to reflect as accurately as possible what it will actually cost the Institution to fulfill its obligations in completing the required Scope of Work in the Study Protocol. The Study Coordinator or their designee completes the budget and submits it to the CTO as part of the Lifespan Business Proposal package. The CTO will then compare the internal budget to the Sponsor budget to verify that the Sponsor's funding offer is adequate to cover Institutional costs.



Resources for Clinical Trial Budgeting:

<http://www.clinicaltrialmagnifier.org/trial-budget/>

https://medicine.umich.edu/medschool/sites/medicine.umich.edu.medschool/files/Res_Grants_Budgeting%20a%20Clinical%20Trial%202012%20Web%20Version.pdf

<http://pharmaceuticalcommerce.com/clinical-operations/get-better-at-managing-clinical-trial-financials/>

<http://www.ehcca.com/presentations/ressummit/503.PDF>

How to complete the form:

The internal budget form is completed by inputting hospital costs on a per-visit basis in a pre-formatted Excel spreadsheet. Each study visit is listed vertically on the left side of the form, and all hospital costs are listed horizontally at the top of the form. These costs include:

1. **Salary and fringe benefits for the physician(s), nurse, coordinator, and any other staff devoting effort to the study:** Salary and fringe is calculated based on the estimated staff time that will be devoted on a per visit basis. Time can be broken down in quarter hour increments.
2. **Hospital costs for any Lifespan labs, scans, or services that will be paid by the Sponsor:** All Lifespan charges for procedures, scans (i.e. MRI, CT, PET), services (i.e. phlebotomy, x-ray, EKG, professional reads, etc.) labs. Please note that all scans must be read before being sent out, even if the scan is being read centrally.
3. **Pharmacy costs if applicable:** for use if the pharmacy is storing and dispensing study drug
4. **Patient stipends, parking etc., if applicable**
5. **Supplies, shipping and other miscellaneous expenses that will be incurred:** This includes patient care supplies not provided by the Sponsor.
6. **Outside services:** Any service being charged to the study that is performed by an outside vendor/organization, including Specialist office visits such as dermatology, ophthalmology, or other outside testing services.

Sponsor Offer: The Sponsor's per patient visit budget is entered on the second from the last column on the right side of the form. The worksheet is formatted in the last column on the right to then calculate the difference between the estimate of the Institution's actual cost and the amount the Sponsor is offering. A negative number indicates the Sponsor budget is too low and must be negotiated to include higher reimbursement amounts.

Pass-through fees: Fees such as IRB, start-up, records storage, screen failures and SAEs are entered in the bottom left corner of the internal budget. Pass-through costs for Lifespan billable services are entered in the bottom right corner of the form. These are patient care costs that are not part of the per-patient visits. They may be miscellaneous fees, or testing that may take place for some patients in certain situations, but are not part of the standard schedule of events for all patients enrolled in the study. The Lifespan cost and the amount offered by the Sponsor for Lifespan billable services are both entered, to ensure the sponsor offer is sufficient to cover actual costs.

In the next issue:

Lifespan Labs and Research MRI/PET Scans and Research The QCT Form



All study personnel are listed on the form, along with the PI name, short title, committee number and Sponsor.

Obtaining Quotes for Lifespan Services: For all studies utilizing Lifespan billable services, quotes from the department providing the service *must be included in the Lifespan Business Proposal package* submitted to the CTO. Quotes for all outside services must be submitted as well, to include a description of the services provided, and total cost. Quotes may be in a letter, memo, or email format.

Research Discounts: Discounts from many Hospital Costs for Lifespan services are available. If a study budget includes Lifespan billable services the study coordinator or their designee should, *before* completing the internal budget, contact the CTO for the applicable research discount, if available. The amount of the test or procedure, minus the research discount, is the amount that should be used on the internal budget form.

The internal budget form is available at <http://www.lifespan.org/grants-and-funding-general-forms.html>. For training information, please contact Gina Johnson, Clinical Trials Compliance Administrator at gjohnson@lifespan.org.

See the next page for a sample Internal Budget.

<Principal Investigator> Alice Smith, MD
 <Short Title of Trial> ABC Study
 <Sponsor> APEX Pharma
 Committee # 1234-16

Industry-Sponsored Clinical Trial
 Internal Budget
 (for Lifespan Internal use only)

LIFESPAN COSTS →

LIFESPAN COSTS →																						
Coordinator Time		Nurse Time		Physician Time		Fringe benefits		Total Time		Supplies	HS Payments	MSU/CT/PT PLUS REG	Serum	Pregnancy	Vasopuncture	OKC	Pharmacy Disp	Direct Costs	Indirect Cost 30%	Total Cost	Sponsor Offer	Difference
# Hrs	Hourly salary	# Hrs	Hourly salary	# Hrs	Hourly salary	Current Rate																
**Insert Staff member hourly salary →																						
Insert visits based upon Protocol Schedule of Events. →	Visit 1	1	\$ 35.00	2	\$ 100.00	0.25	\$ 37.50	\$ 46.58	\$ 219.08	\$ 100.00	\$ 35.00			\$ 7.00	\$ 4.00	\$ 14.00	\$ 11.00	\$ 390.08	\$ 117.02	\$ 507.10	\$ 1,000.00	\$ 492.90
	Visit 2	0.5	\$ 17.50	0.25	\$ 12.50	0.25	\$ 37.50	\$ 18.23	\$ 85.73		\$ 35.00	\$ 500.00					\$ 11.00	\$ 631.73	\$ 189.52	\$ 821.24	\$ 1,000.00	\$ 178.76
	Visit 3	0.25	\$ 8.75	0.75	\$ 37.50	0.25	\$ 37.50	\$ 22.61	\$ 106.36		\$ 35.00						\$ 11.00	\$ 152.36	\$ 45.71	\$ 198.07	\$ 500.00	\$ 301.93
	Visit 4	1	\$ 35.00	1	\$ 50.00	0.25	\$ 37.50	\$ 33.08	\$ 155.58		\$ 35.00						\$ 11.00	\$ 201.58	\$ 60.47	\$ 262.05	\$ 500.00	\$ 237.95
	Visit 5		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 6		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 7		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 8		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 9		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 10		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
	Visit 11		\$ -		\$ -		\$ -	\$ -	\$ -									\$ -	\$ -	\$ -	\$ -	\$ -
Total Cost		2.75	\$ 96.25	4	\$ 200.00	1	\$ 150.00	\$ 120.49	\$ 566.74	\$ 100.00	\$ 140.00	\$ 500.00	\$ 7.00	\$ 4.00	\$ 14.00	\$ 44.00	\$ 1,375.74	\$ 412.72	\$ 1,788.46	\$ 3,000.00	\$ 1,211.54	

Total Direct Costs (Full Enrollment) See column R	Enrollments =	1	\$1,375.74
IRB Initial Fee		1	\$3,500.00
Pharmacy Administrative Fee		1	\$1,300.00
Record Maintenance		1	\$650.00
Start Up Fee (one time only)		1	\$5,000.00
Study/IRB Close-Out Fee		1	\$2,000.00
Total Direct Costs for Study			\$13,825.74
Total Indirect Costs (30%)			\$412.72
Total Study Budget			\$14,238.46

Personnel	
John Smith	Coord.
Jane Smith, RN	Nurse
Alice Smith, MD	PI
Robert Smith, MD	Sub-I

Pass-through Conditional

Tests and Procedures:

** not part of per patient budget;
 performed on as needed basis

Name	Lifespan Cost	Sponsor Offer	Difference
eye exam	156.00	175.00	19.00

Conditional Pass-through costs (Invoicable as they occur)		
IRB Annual Review	per year	\$1,500.00
IRB Fee / Sponsor Protocol Change	per protocol change	\$750.00
Advertising Fee	as needed	\$5,000.00
Screen Failure(s)	per screen failure	\$1,000.00
SAE Reports	per report	\$25.00