I. SCOPE

These guidelines are applicable to all sponsored clinical trials performed by LUMC or LUC Investigator(s) or Principal Investigator(s), regardless of the site where the research is done. "Clinical Trials", a "Study", or "Studies" for the purpose of this document are defined as any investigation involving human subjects or human tissue samples. All such studies (except material transfer agreements) require review and approval by the Institutional Review Board (IRB) as described in the IRB policies and procedures. Funding mechanisms may include:

1. Commercial (industry)
2. Federal (including sub-awards)
3. Nonprofit, Foundation
4. Internal

II. PROCEDURES

A. Industry

1. Guidelines
   a. The budget is considered part of the final executed clinical trial agreement and includes all projected costs associated with the conduct of the study.
   b. The Coverage Analysis (CA) is your primary source for determining clinical items and services that will be billed to the sponsor and should be included in the budget.
   c. The internal charge for the clinical items and services are consistent with the LUMC pricing structure policy (Medicare plus 35%).
   d. Investigator, research nurse and coordinator and other study personnel effort should be built into the budget as a separate line item and clearly delineated if performing an otherwise billable item or service (such as venipuncture).
   e. Outpatient clinic and facilities fees should be captured in the sponsor budget for research only visits.
   f. Include all applicable overhead fees.
   g. For multi-year projects, include an annual inflation factor.
2. Process
   a. The department (administrator or study team) is responsible for developing a cost based analysis for all commercially sponsored clinical trials.
   b. Sponsor provides a proposed budget.
   c. Compare the sponsor proposed budget to cost-based budget.
   d. Determine minimal acceptable cost (cannot be less than actual internal cost).
   e. Ensure non-refundable startup costs are included.
   f. Negotiate budget with sponsor.
   g. Submit to the Clinical Research Office (CRO) for final approval of all clinical research budgets.
   h. The CRO will send the final approved budget to the LUC Office of Contract Administration.
   i. The LUC Office of Contract Administration is responsible for facilitating review of the payment terms to ensure consistency with the budget and associated fees.
   j. Receipt of the final contract (including the budget) and final approval will be facilitated and tracked by the LUC Office of Contract Administration.
   k. The LUC Office of Contract Administration will process and upload the executed CTA and budget in the Research Portal.

B. Federal / Non-profit

1. Guidelines
   a. Because the guidelines for budgeting patient care costs may vary from sponsor to sponsor, it's important to review sponsor-specific guidelines to determine policy and

allowability in relation to a given grant application. The National Institutes of Health, for example, addresses research patient care costs within the NIH Grants Policy Statement.

b. While the NIH policy is essential to those completing NIH applications and provides a good, general indication of the overarching federal requirements, the guidelines within the NIH policy may or may not be entirely applicable to other federal agency applications or to state or private funding sources. Therefore, applicants should always review sponsor-specific guidelines before preparing a budget.
c. Include all applicable Facilities and Administrative fees (F&A).
d. For multi-year projects, include an annual inflation factor.
e. When LUC is prime recipient, confirm and include all sub-award site costs.
f. Research Administration in the Office of Research Services can provide budget development support.

2. Process
   a. The department (administrator or study team) is responsible for developing a cost based analysis for research that involves human subjects.
   b. The Coverage Analysis (CA) is your primary source for determining clinical items and services that will be billed to the study and should be included in the budget documents. You do not have to attach this to the application.
   c. NIH provides the following guidance on patient care costs: If inpatient and/or outpatient costs are requested, the following information should be provided:
      (1) The names of any hospitals and/or clinics and the amounts requested for each.
      (2) If both inpatient and outpatient costs are requested, provide information for each separately.
      (3) Provide cost breakdown, including number of days, number of patients and costs of tests/treatments.
      (4) Research patient care costs should be budgeted at the Medicare rate.
      (5) Justify the costs associated with routine care or research patient care.
   d. Budget proposals should be sent to ORS Grant Administrators for final approval.

C. **Internally Funded**
1. Guidelines
   a. The internal costs for the clinical items and services are consistent with the LUMC pricing structure policy (Medicare rates).
   b. Investigator, research nurse and coordinator effort should be built into the budget as a separate line item and clearly delineated if performing an otherwise billable item or service (such as venipuncture).
   c. Outpatient clinic and facilities fees should be captured in the sponsor budget for research only visits.
   d. For multi-year projects, include an annual inflation factor.
2. Process
   a. The department (administrator or study team) is responsible for developing a cost based analysis for research that involves human subjects.
   b. The Coverage Analysis (CA) is your primary source for determining clinical items and services that will be billed to the study and should be included in the budget documents.
   c. Submit the budget to your department chair and/or administrator for approval.
   d. The department chair and/or administrator will complete the Internal Funding Approval Memo and submit to the CRO.
   e. The CRO will send the final approved Internal Funding Request and Approval Form to the LUC Office of Contract Administration.

III. REFERENCES

A. CR-001 Pricing Structure for Sponsored Clinical Research Studies Policy
B. FIN-001 Coverage Analysis Development SOP
C. NIH Grants Policy Statement
D. LUMC / LUC Operational Assessment and Study Startup Checklist

IV. ASSOCIATED DOCUMENTS AND FORMS

A. Internal Funding Request and Approval Form
B. Budget Checklist
C. Industry Budget Quick Guide (Recommended fees for Industry startup and non-CPT related research activities)
D. Industry Budget Template

V. APPROVALS

8/30/16
LUMC Director, Research Operations Office (or designee) Date

08/30/2016
LUC Senior Director, Clinical Research Office (or designee) Date

LOYOLA UNIVERSITY HEALTH SYSTEM

LOYOLA UNIVERSITY CHICAGO

INTERNAL FUNDING REQUEST AND APPROVAL FORM

Department:
Name of Investigator:
Phone Number:
LU#:
AU#:

Project Title:

Project Summary:

Proposed start date:
Estimated completion date:

Budget (Provide budget information below or attach a separate budget worksheet.)
- Personnel Salary:
- Fringe Benefits:
- Travel:
- Patient Care Cost:
- Supplies:
- Other Cost:

Total amount requested:

Budget Justification (Briefly describe the rationale for the above listed costs.)

Verification and Approvals

By signing below, I am confirming all applicable study costs are included in the budget.

_____
Principal Investigator Date

By signing below, I am authorizing internal department funds in the amount listed above to support this research project.

_____
Department Chair / Administrator Date

By signing below, I am confirming all applicable study costs are included in the budget.

_____
CRO Senior Director Date

BUDGET CHECKLIST

Start-up costs (non-refundable)

- ☐ Regulatory preparation and submission
- ☐ Contract review and negotiation
- ☐ CA Development
- ☐ Source document and CRF development
- ☐ Communication with the sponsor
- ☐ Pharmacy start up and closeout costs
- ☐ Investigator meeting
- ☐ Protocol review
- ☐ Study specific training

Per-participant costs

- ☐ Principal Investigator time
- ☐ Study Coordinator time
- ☐ Tasks
- ☐ Vital signs, inclusion/exclusion, etc.
- ☐ Procedures
- ☐ Activities, based on flow chart
- ☐ Laboratory tests
- ☐ Participant incentives
- ☐ Administrative work
- ☐ Facility Fees

Invoiceables / Variable costs

- ☐ AE/SAE reporting
- ☐ Shipping
- ☐ Supplies
- ☐ Printing
- ☐ Audits
- ☐ Monitor visits
- ☐ Sponsor interactions
- ☐ Participant reimbursement (travel, meals, etc.)
- ☐ Advertising
- ☐ Study specific phone lines
- ☐ Screen failures (pro-rated)
- ☐ Study specific training
- ☐ Protocol amendments
- ☐ Contract amendments

BUDGET QUICK GUIDE

Recommended Fees for Industry Sponsored Studies

NON-REFUNDABLE STARTUP FEES	Charge	Indirect 26%	Total
Administrative Fees			
CDA/NDA: Site Qualify Visit	900.00	234.00	1,134.00
Site Initiation Visit	1,600.00	416.00	2,016.00
Coverage Analysis	2,500.00	650.00	3,150.00
Budget Preparation	1,000.00	260.00	1,260.00
Specialized Training/Education Training	1,000.00	260.00	1,260.00
Regulatory Fees			
Consent Preparation	1,500.00	390.00	1,890.00
IRB Initial Review	3,000.00	0.00	3,000.00
Other Fees			
Pharmacy Start Up Fees	1,000.00	260.00	1,260.00
TOTAL	**12,500.00**	**2,470.00**	**14,970.00**

INVOICEABLE FEES	Charge	Indirect 26%	Total
Additional Language or Optional Participation Consent	1,500.00	390.00	1,890.00
IRB Annual Review Preparation Fee	950.00	247.00	1,197.00
Annual Pharmacy Fee	270.00	70.20	340.20
Budget / Contract Amendment Fee	500.00	130.00	630.00
Protocol / CA Amendment Fee	800.00	208.00	1,008.00
Monitor Visit Prep Fee	760.00	197.60	957.60
AE/Safety Letter Fee	45.00	11.70	56.70
Local Safety Letter Fee/SAE	500.00	130.00	630.00
Archival/Storage Fee	500.00	130.00	630.00
Close Out Fee	650.00	169.00	819.00
Audit Prep Fee	1,000.00	260.00	1,260.00

OTHER RECCOMMENDED FEES *(Non-CPT Research Activities)*	**Charge**	**Indirect 26%**	**Total**
Parking	5.00	0.00	5.00
Dry Ice	25.00	0.00	25.00
Adverse Events	50.00	13.00	63.00
Assessments	75.00	19.50	94.50
Central Labs	75.00	19.50	94.50
Randomization	100.00	26.00	126.00
Concomitant Meds	25.00	6.50	31.50
Inclusion / Exclusion Criteria	100.00	26.00	126.00
Height and Weight	15.00	3.90	18.90
History and Demographics	150.00	39.00	189.00
Informed Consent	150.00	39.00	189.00
Phone Call	50.00	13.00	63.00
PK Blood Sample Draw	75.00	19.50	94.50
Questionnaires	75.00	19.50	94.50
Safety Lab Tests	75.00	19.50	94.50
Study Drug Administration (Research Staff)	150.00	39.00	189.00
Subject Diary Data Input	50.00	13.00	63.00
Urine Sample Send Out	50.00	13.00	63.00
Vital Signs	25.00	6.50	31.50

BUDGET TEMPLATE FOR INDUSTRY SPONSORED STUDIES

LOYOLA UNIVERSITY CHICAGO

LOYOLA UNIVERSITY HEALTH SYSTEM

LU#:
PI:
Sponsor:
Protocol #:
Title:

NON-REFUNDABLE STARTUP FEES	Cost	Indirects 26%	Total
Consent Preparation Fee	0.00	0.00	0.00
Budget Preparation Fee	0.00	0.00	0.00
CA Development Fee		0.00	0.00
Set-up Fee (initiation and template)	0.00	0.00	0.00
Pharmacy Review - Initial	0.00	0.00	0.00
Pharmacy Annual Review	0.00	0.00	0.00
IRB Fee	3,000.00	0.00	3,000.00
Advertisement Fee - as appropriate	0.00	0.00	0.00
TOTAL			**3,000.00**

STUDY COSTS PER PARTICIPANT	CPT code	Cost per Unit	# Events	Cost	Indirects 26%	Total
test 1		0.00	1	0.00	0.00	0.00
test 2		0.00	1	0.00	0.00	0.00
test 3		0.00	1	0.00	0.00	0.00
test 4		0.00	1	0.00	0.00	0.00
Subtotal Study Costs Per Participant		**0.00**			**0.00**	**0.00**

PERSONNEL COSTS PER PARTICIPANT	Hourly Rate	# Hours	Subtotal	Indirects 26%	Total
Investigator salary	0.00	0.00	0.00	0.00	0.00
Coordinator salary	0.00	0.00	0.00	0.00	0.00
Nurse salary	0.00	0.00	0.00	0.00	0.00
Subtotal salaries and benefits			**0.00**	**0.00**	**0.00**

Note: The hourly rate should include salary and fringe benefits.

TOTAL PER PARTICIPANT COSTS **0.00**

BUDGET TEMPLATE FOR INDUSTRY SPONSORED STUDIES

LU#:
PI:
Sponsor:
Protocol #:
Title:

LOYOLA UNIVERSITY CHICAGO | LOYOLA UNIVERSITY HEALTH SYSTEM

NON-REFUNDABLE STARTUP FEES

Description	Cost	Total
Consent Preparation Fee		0.00
Budget Preparation Fee		0.00
Set-up Fee (initiation and template)		0.00
CA Development Fee		0.00
Pharmacy Review - Initial		0.00
Pharmacy Annual Review		0.00
IRB Fee		0.00
Advertisement Fee - as appropriate		0.00
Total Startup Fees		**0.00**

PER PARTICIPANT COSTS

			Visit Number				
Procedure Description	Unit Cost ($)	Unit Cost ($) (w/ Overhead)	1	2	3	4	5
	$ 100.00	$ 126.00	1.0	1.0	1.0	1.0	1.0
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
		$ -					
Total Per Patient			$ 126.00	$ 126.00	$ 126.00	$ 126.00	$ 126.00

OTHER COSTS

Description	Unit Cost ($)	Unit Cost ($) (w/ Overhead)	Number Units	Total Cost
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
		$ -		$ -
Total Other Costs				$ -

NOTES

Overhead % Applied: 26.0%

Startup Fee	0.00
Per Participant Cost	630.00
Other Costs	0.00
# Participants	10
TOTAL BUDGET	**$ 6,300.00**