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Owner	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies
Department	HRPP/Research

Research: Clinical Trial Feasibility- AD.0153

PURPOSE

The purpose of this policy is to ensure that for each proposed research study/clinical trial, Lakeland Regional Health (LRH) is able to determine whether the proposed trial is financially feasible, appropriately billed to Medicare or other applicable payors and accounted for according to applicable guidelines (**NIH** or other government/sponsor requirements), and tracked for internal and other record-keeping requirements. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This policy applies to Lakeland Regional Health's **Workforce** and personnel engaged in research.

POLICY

I. Background

A. Medicare covers the routine costs of qualifying clinical trials, as such costs are defined below, as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. All other Medicare rules apply.

B. Routine costs of a clinical trial include all items and services that are otherwise generally available to Medicare beneficiaries (i.e., there exists a benefit category, it is not statutorily excluded, and there is not a national non-coverage decision) that are provided in either the experimental or the control arms of a clinical trial except:

1. The investigational item or service itself unless otherwise covered outside of the clinical trial;
2. Items and services provided solely to satisfy data collection and analysis needs and that are not used in the direct clinical management of the patient (e.g., monthly CT scans for a condition usually requiring only a single scan); and
3. Items and services customarily provided by the research sponsors free-of-charge for any enrollee in the trial.

C. Routine costs in clinical trials include:

1. Items or services that are typically provided absent a clinical trial (e.g., conventional care);
2. Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and
3. Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service in particular, for the diagnosis or treatment of complications.

II. Policy

A. Specific documentation is required by LRH to determine, prior to the start of the research study and/or admission of the first patient into the clinical trial, whether the trial qualifies for Medicare reimbursement under the Medicare clinical trial billing guidelines, and is accomplished according to the following procedures:

B. IRB Review Fees

1. All studies that are reviewed by the LRH IRB are subject to IRB review fees. An IRB review fee is an assessment of real costs associated with protocol review by the IRB and is charged regardless of IRB approval. The review fees are assessed for all external studies (originating Principal Investigator (PI) is a non-LRH agent).
    i. The administrative fee will be charged for all administrative reviews, such as ceded reviews and closures.
2. The amount of all fees will be reviewed annually by the Institutional Officer (IO) and are subject to change.
3.

Review Type	Fee
Initial Review	$3,000.00
Expedited Initial Review	$2,000.00
Annual Continuing Review	$1,200.00
Expedited Continuing Review	$600.00
Amendment/Modification Fee*	$300.00 - $600.00
Protocol Deviation/On-Site Serious Adverse Event Fee*	$300.00 - $600.00
Administrative Fee	$300.00

*variable depending on level of review

PROCEDURE

I. **The Principle Investigator will be responsible for providing the following documents/information to the LRH IRB:**

A. Clinical Trial Pre-IRB Cost Estimate (sample form attached);

B. Breakdown of all revenues and expenses associated with the trial if not included in the form listed above;

C. A copy of the **FDA** letter to the manufacturer assigning an Investigational Device Number (IDE#) or Investigational New Drug Number (IND#) and approving the study;

D. A copy of the manufacturer's letter enrolling LRH, or the Principle Investigator in the approved study;

E. A copy of the clinical trial protocol, patient selection protocol, and number of patients allotted to the Principle Investigator;

F. Any information from the study sponsor or granting agency on specific requirements related to the accounting of funds associated with the trial/grant;

G. Clinical Trial Patient Tracking Form (see attached); and

H. Any other pertinent information.

II. **Financial Feasibility**

A. The Principal Investigator will provide the Financial Feasibility Committee with a breakdown of all revenues and expenses anticipated to be associated with the trial, including the information included on the Clinical Trial Pre-IRB Cost Estimate form, and any other information available that would impact the cost of the study. For those studies with reimbursement from sponsors, the Finance, Legal and Research Departments will work with the PI to ensure that the Clinical Trial Agreement covers all appropriate costs at LRH.

B. LRH has established a Facilities and Administration cost rate that is housed in Finance and updated when warranted. This rate will be included on all sponsored studies unless the Financial Feasibility Committee determines otherwise and will be provided to the Principal Investigator prior to submission.

C. In addition, all studies will be subject to an IRB fee schedule, (see above). These fees will also be included in each study unless an administrative waiver is sought and approved.

a. Fee waivers will be considered on a case-by-case basis and the determination will be made by the appropriate employees of the Department of Research and Sponsored Studies.

D. In the event that the analysis reveals LRH will incur a loss on the study that grossly contradicts the research mission of LRH, the Financial Feasibility Committee will work with the Research Department and PI to determine whether the trial is operationally/strategically viable.

III. **Research Cost Sharing**

A. LRH encourages research throughout the organization and focuses on supporting projects that will be impactful and contribute to knowledge and excellence in patient care. Recognizing that some research studies may meet these criteria but are not fully funded, or that some sponsors may mandate sharing of costs, LRH may commit resources to a research project/ study from a pool of funds if the study aligns with strategic priorities of the LRH Research Department and the organization overall.

IV. **Medicare Billing**

A. The Business Office (Billing and Revenue Cycle) will be provided with the Clinical Trial Pre-IRB Cost Estimate, the FDA letter, manufacturer enrollment letter, the clinical trial protocols, correspondence from **CMS** for the clinical trial at LRH to alert billing that a new trial is coming. Upon receipt of these materials, the Business Office will review and determine the Medicare billing status of the study and the inherent items/services provided to the research subjects as part of the study. This process is called a Medicare coverage analysis review and serves to ensure all costs of a clinical trial are billed to the appropriate payer. This process is used to establish a tool that is used for both the Business Office and Research Department when conducting a clinical trial.

B. As patients enrolled in the clinical trial receive services, a Clinical Trial Patient Tracking Form (or other tracking process) will be completed by the PI or study coordinator and sent to the billing/coding department. This form aids the biller/coders of which items/services were rendered and how they are to be billed as previously determined in the Medicare coverage

analysis.

C. There are a variety of ways in which LRH may receive compensation for conduct of a clinical trial. There are three (3) main ways: 1) directly generated by the sponsor for particular milestones achieved; 2) standard billing practices; and 3) invoicing the sponsor for services rendered. The Research Department and Business Office will determine the responsibilities of obtaining compensation, which may involve actions from one or both departments depending on the protocol. In the event there are items LRH is unable to bill Medicare or other payors for, the Business Office will be responsible for invoicing and negotiating reimbursement from the study sponsor.

V. **Fund Tracking**

A. The study sponsor will work with a member from the Business and/or Finance Office to understand any financial reporting requirements placed on LRH by a governmental agency, study sponsor or granting entity. Revenues and expenses will be tracked in accordance with these requirements. In addition, activity codes will be set up for each study by the accounting department and used to track each trial's revenue and expenses. Finance/Accounting will also assist in producing any other financial information that may be necessary such as the development of indirect cost rates.

VI. **Study Reimbursement**

A. All payments made from the study sponsor related to an approved study will be received by the Finance Department of LRH. The Finance Department will then ensure that study investigators are paid according to the protocol and cost estimator form/budget. Finance will also ensure that all study revenues and expenses are tracked for each study as outlined above.

VII. **Annual Review of Study**

A. Each study approved by the IRB for research at LRH is reviewed annually to ensure that the study is still active. One month prior to the annual IRB review of any study, the IRB Administrator will notify Finance of the upcoming review to ensure that the research study billing and investigator payments are up to date. This will ensure that no payments or reimbursement will be missed, should the IRB determine that a study should be closed.

DEFINITIONS

CMS: Centers for Medicare and Medicaid Services

FDA:Food and Drug Administration

IRB:Institutional Review Board

MAC:Medicare Administrative Contractor

NIH:National Institutes of Health

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

Lakeland Regional Medical Center Clinical Trial Pre-IRB Cost Estimate

LRH Clinical Trial Pre-IRB Cost Estimator	
Date issued:	Submission date for IRB:
Sponsoring Organization:	Performing Organization:

Trial Number/Name:	Principal Investigator:
Expected Number of Patients:	Length of Patients Participation: Active: Follow Up:
LRH inpatient	LRH outpatient
Does this study involve a device? If yes, please complete below.	
Is the device FDA approved?	If the device Investigational?
Is the device Post Market?	Is the device reimbursable?
Is the device provided by the Sponsor?	

Which of the following LRH departments are involved? Please sign to signify that the Protocol has been reviewed.

Department	Protocol Page #	Additional Req.	Signature	Date
Laboratory				
Pathology				
Pharmacy				
Radiology				
Cath Lab				
Nursing				
Education				
Purchasing				

RISK MANAGEMENT

Sponsor Liability:	
Indemnification:	
LRH Liability:	
Patient Liability:	
Risk Management Approval:	

LABORATORY

To be completed by the Research Coordinator:		**To be completed by the department:**
In house lab?	SOC?	Estimated staff involvement per dept., including training.

If not SOC, is the sponsor covering the lab charges?	Time impact?
Which labs will the sponsor cover?	Cost of staff time?
Study labs?	Administrative time?
Requirement for LRH staff time?	Supplies?
Any storage requirement?	Additional comments?

PATHOLOGY

To be completed by the Research Coordinator:	**To be completed by the department:**
Pathology/Histology required?	Estimated staff involvement per dept., including training.
If yes, how many blocks?	Time impact?
If blocks are not available, can slides be substituted?	Cost of staff time?
Requirement for LRH staff time?	Administrative time?
Any storage requirements?	Supplies?
What will sponsor pay?	Additional comments?

PHARMACY

To be completed by the Research Coordinator:						**To be completed by the department:**
Is there an investigational agent involved?						Time impact?
Will the Sponsor pay pharmacy start up costs?						Cost of staff time?
Is the drug supplied by the Sponsor?						Administrative time?
Are there SOC drugs involved?						Supplies?
Drug	HCPCS	Freq.	#units	Unit cost	total cost	
						Additional comments?
LRH staff time?						
Storage?						

RADIOLOGY

To be completed by the Research Coordinator:	**To be completed by the department:**

Are there scans that are not SOC care involved?						Time impact:
If yes, please list below:						Cost of staff time?
Test	CPT	Freq	Total units	Unit cost	Total cost	Administrative time?
						Supplies?
What will the sponsor pay?						Additional comments?
LRH staff time?						
Storage?						

CATH LAB

To be completed by the Research Coordinator:						**To be completed by the department:**
Are there any tests which are not SOC?						Time impact:
If yes, please list below						Cost of staff time?
TEST	CPT	Freq	Total cost	Unit cost	Total cost	Administrative time?
						Supplies?
LRH staff time?						Additional comments?
Storage?						
What will sponsor pay?						

NURSING

To be completed by the Research Coordinator:						**To be completed by the department:**
Are there any procedures which are not SOC?						Time impact:
If yes, please list below						Cost of staff time?
Procedure	CPT	Freq	Total cost	Unit cost	Total cost	Administrative time?
						Supplies?
LRH staff time?						Additional comments?
Storage?						
What will sponsor pay?						

EDUCATION

To be completed by the Research Coordinator:	To be completed by the department:
Any teaching which is not SOC?	Time impact:
If yes, please describe:	Cost of staff time?
	Administrative time?
	Supplies?
LRH staff time?	Additional comments?
Storage?	
What will sponsor pay?	

PURCHASING

To be completed by the Research Coordinator:	To be completed by the department:
Market price analysis?	Has a market analysis been conducted?
Consignment?	If yes, please provide the staffing requirement?
Sponsor preferred pricing?	
Are there any procedures which are not SOC?	What impact will this have on existing vendor contracts and preference of p
If yes, please list below	

Device/Drug	CPT	Freq	Total cost	Unit cost	Total cost

LRH staff time?	Has the sponsor agreed to a preferred pricing plan?
Storage?	
What will sponsor pay?	
	Is this a feasible study for LRH to participate in?
	If pricing favorable to LRH?
	Will the device have appropriate billing codes already established in the hos If not, please explain?
	Is CDM setup required?

	What will the sponsor pay?

Attachments

Clinical Trial Patient Tracking Form.docx

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	01/2023
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	01/2023
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	01/2023
	Renee Reed: 4064 Senior Attorney	01/2023
	Lance Green: 0005 Executive Vice President/Chief Financial Offi	12/2022
	John Frizzell: 0095 Controller	11/2022
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	11/2022
	Susanne Suldickas: 4300 AVP - LRHPG Revenue Cycle	11/2022
	Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	10/2022
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	10/2022
	Danielle Hart: 4388 Institutional Review Board Administrator	09/2022