

**Louisiana State University
Health Care Services Division
Baton Rouge, LA**

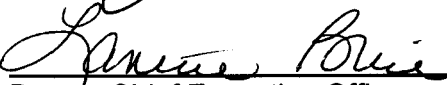
Policy Number: 10003-11
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Interim Chief Executive Officer
LSU Health Care Services Division

11.9.11


Date



Deputy Chief Executive Officer
LSU Health Care Services Division

11/7/11

Date



Chief Medical Officer
LSU Health Care Services Division

11/3/11

Date



Director, Sponsored Projects
LSU Health Care Services Division

10/18/11

Date

Purpose and Scope:

The purpose of this policy is to establish minimum uniform billing requirements and conditions when a Louisiana State University Health Care Services Division (HCSD) hospital is authorized to participate in research activities.

This policy applies to HCSD Headquarters and all HCSD hospitals and employees and medical staff/faculty regardless of medical school affiliation who conduct research in HSCD hospitals.

Policy Statement:

- a. It is the policy that all HCSD hospitals faculty, providers and staff work collaboratively with the sites of practice plans to ensure that billing for costs incurred in the conduct of research activities occur only as appropriate and in compliance with relevant laws and regulations.
 - i. Any billing to Medicare, Medicaid, another third party insurer, or to the research subject for professional or clinical services, drugs, devices or tests provided in the context of clinical research study must be:
 - ii. specifically allowable by applicable federal and state laws and regulations governing medical billing practices, by other third-party payor requirements
 - iii. specifically allowable with any contractual obligations entered into by HCSD or sites of practice, and
 - iv. fully disclosed in the Informed Consent Document signed by the research subject.
- b. It is the policy of HCSD that each clinical study will be charged and coded based on the actual services rendered. The documented billing plan developed as part of the detail study budget will serve as a guide of how charges will be directed to the appropriate responsible party:

The billing plan will:

- 1) Delineate the services, drugs, devices, and tests to be rendered in the context of the clinical study;
 - 2) Identify which services, drugs, devices, and tests must be billed to the study, or which are appropriate to be billed to the patient or the patient's insurer (See Appendix B); and
 - 3) Be updated and provided to appropriate billing staff at the appropriate site of practice if amendments are made to the contract or protocol.
 - 4) It is the policy of HCSD that all study related documents will contain specific statements with respect to the services that will be provided by the sponsor and which services will be billed to a third party payer or the research subject.
 - 5) It is the policy of HCSD that all faculty, providers and staff shall follow the safeguards established by HCSD and each practice site to ensure that all rendered services and items are billed and reimbursed appropriately.
- c. It is the policy of HCSD that all study subjects receiving procedures for clinical research purposes at any HCSD hospital are properly identified and classified for appropriate billing and reimbursement.

Procedure

The Principal Investigator (PI), department chair or designee and Research Oversight Committee will work collaboratively with staff at the Central Billing Office in order to

ensure compliance with the rules for billing federally funded health programs and third party payers for services, drugs, tests and procedures rendered in the clinical research context. As individual facilities have unique operations, each site of practice is granted the right to develop its own written procedures to address how it will meet the requirements of this policy. It is the PI's responsibility to inquire about the particulars of that policy at the site of interest. The responsibilities of the PI are as follows:

- Develop a detailed budget (Appendix A) with billing plan (Appendix B)
- Ensure that all study related documents contain specific language regarding which costs will be reimbursed by the sponsored project and which services will be billed to a patient or the patients insurer
- Establish safeguards to ensure that all charges are billed appropriately, including tracking all study related services and checking them against invoice reports prior to billing
- Report any billing concerns to the appropriate billing staff for review and/or correction.
- Follow all other clinical research implementation and billing procedures determined by the site of practice.

Audit & Compliance Requirements

It is the intent of HCSD and the sites of practice to bill clinical research activities appropriately. Therefore, alleged violations of this policy shall be reported to the Compliance office. This includes billing issues that have been reported but remain unresolved. Allegations will be addressed in a timely manner by the appropriate compliance office staff.

Failure to Comply

1. Hospital

Failure to comply with this policy could result in the refund of current sponsored project money, as well as the loss of future clinical research opportunities.

2. Principal Investigator

Failure to comply with this policy could result in the loss of research privileges at the sponsoring LSU-HCSD hospital. If the failure to comply with the policy reveals misconduct on the part of the PI, the matter will be referred to the hospital administrator and medical staff for disciplinary action up to and including the termination of medical staff privileges.

3. Employees

Any employee, who is found to have intentionally violated this policy or the procedures of the hospital, as they relate to clinical trials /clinical research, may be subject to disciplinary action, up to and including termination of employment in accordance with hospital regulations, the rules of the Department of State Civil Service and/or LSU-HCSD policies.

Definitions:

- A. Sponsored Project: Services/programs/activities underwritten by an external organization (governmental or nongovernmental). Awards can be "financial" or

“non-financial,” research or non-research, and are intended to fulfill a general purpose identified by the sponsoring agency.

B. Types of Sponsored Projects:

- **Grant:** award for assistance to provide services, supplies, or equipment, to conduct research or for education purposes.
- **Sub-recipient Agreement:** agreement with a primary grantee.
- **Interagency Transfer Agreement (IAT):** agreement between two or more state agencies for the purposes of transferring funds, property or services
- **Intra-Agency Agreement:** agreement within different entities in the same state agency.
- **Memorandum of Understanding (MOU):** a simple agreement of cooperation between two organizations defining the roles and responsibilities of each organization in relation to the other
- **Contract:** a written legal agreement, enforceable by laws and signed by two or more parties for the fulfillment of expressed obligations, including services to be provided, time periods, terms of payment, and other terms and conditions as are appropriate and which are mutually agreed upon.
- **Clinical Research:** a clinical trial, study or other research sponsored by a private sponsor, nonprofit foundation, governmental agency, or other funding source, which is designed to test the safety, and/or therapeutic, diagnostic, or preventive interventions that may eventually be used in humans.
- **Gift:** a donation of tangible or intangible property in which there is no expectation of a benefit to the donor.
- **Other:** Any use of HCSD resources; staff, space, supplies, by any non-HCSD entity
 - Example:
 - Surveys
 - Data collection or reporting
 - Dedication of “in-kind” HCSD resources toward any project sponsored by a non-HCSD entity
 - HR services to hire staff and accounting services
 - Use of computer equipment
 - Use of state employee toward grant activities

C. Principal Investigator (PI)--in research, the person who directs a research project or program. The principal investigator (the PI) usually writes and submits the grant application, oversees the scientific and technical aspects of the grant, and has responsibility for the management of the research.

D. Bill –A bill is the actual claim presented to one or more sponsors for reimbursement. It may contain all the charges associated with the rendered services, or only some of them.

E. Charge–Each service or item in the hospital charge description master lists a price. Charges are those prices associated with the services rendered.

F. Clinical Research (as defined for this policy): A study designed to assess the safety and/or efficacy of drugs, devices, diagnostics, treatments, or preventative measures in humans.

G. Federal Health Care Programs: Any plan or program that provides health benefits whether directly, through insurance or otherwise, which is funded directly, in whole or in part, by the United States Government or a State health benefit program (with the exception of the Federal Employees Health Benefits

Program) (section 112B(f) of the Act). The most significant Federal health care programs are Medicare, Medicaid, Tricare, and the Veterans programs.

References:

CMS National Coverage Decision for Routine Costs in Clinical Trials, 2000

Appendices

Appendix A Clinical Trial/Research Study Budget Worksheet

Appendix B HCSD Research Billing Plan Form

LSU – HCSD CLINICAL TRIAL/ RESEARCH STUDY BUDGET WORKSHEET

CLINICAL TRIAL / STUDY NAME: _____

SPONSORING COMPANY: _____ **SPONSORING DOCTOR (Principal Investigator):** _____

ESTIMATED # OF PARTICIPANTS: _____ **TIME FRAME (M/Y):** _____ to _____ **Inpt** **Outpt** **Telemonitor (circle)**

Similar Trial/Study currently or past participation at hospital? Yes No If yes, identify: _____

Research/Program Coordinator to complete the following for all Clinical Trials/Studies

Part I. Clinical Trial / Study with 25 or less participants per year (COST: CHARGE)

A. Utilization of Hospital Staff

PERSONNEL	% of Time	# Hrs/Week	# Hrs/Month	# Hrs/Year	Hourly \$ Rate	\$ / Week	\$ / Month	\$ / Year
Research Coordinator			0	0		0	0	0
RN Practitioner			0	0		0	0	0
Clerk			0	0		0	0	0
PI (if employed by hosp.)			0	0		0	0	0
Other:			0	0		0	0	0
Other:			0	0		0	0	0
Other:			0	0		0	0	0
Other:			0	0		0	0	0
Educational Leave*				0				0
Travel Expense*								
TOTALS			0	0		0	0	0

* Note only if hospital is incurring expense or if Educational Leave is utilized by employee

TOTAL \$ AMOUNT PER YEAR _____

Part II. Clinical Trial / Study with 26 or more participants or if original number of participants from Part I increases to 35 participants (contact Angie Brown at HCSD (225) 922-0982 to determine if part C, D, E is required)

C. Utilization of Hospital Space

1. Amount of square footage of clinic / hospital for participant study _____
2. Amount of time per MINUTES / HOUR participant will be regularly followed – up (circle) _____
3. Amount of time per WEEK / MONTH participant will be followed-up (circle) _____
4. Anticipated number of participants for this study (remainder - 26 or greater) _____

Indirect / Direct Cost per square foot: _____

D. Other Costs (If applicable)

1. Capital Equipment
Type: _____ Approx. Cost _____
2. Transportation Costs (deliver lab specimens, etc.) per participant
Type: _____ Approx. Cost _____

Total Other Costs per Participant _____

E. Will there be additional funding from a source, if so please specify. _____

Clinical Trial / Study Budget Worksheet Part II Completed by: _____

Signature of Research/Program Coordinator

Financial Class: E (G – MCLNO)

Trial/Study Account Number: _____

Sponsoring Company Account Number: _____

PROPOSED CLINICAL TRIAL/STUDY BUDGET REVIEWED & ACCEPTED YES NO

Signature of CFO or Designee *Date*



LSU HCSD Research Billing Plan Form

This form is required for all research conducted within the LSU Hospital System and must be submitted to the Research Oversight Committee along with the protocol and consent form. If a section is not applicable to your research project, please leave it blank and skip to the next applicable section. For general information regarding the completion of this form, contact the LSU HCSD at (225) 925-4189 or hcsdresearch@lsuhsc.edu

1. Demographic Information		
IRB #		Dept:
Title of Study:		
Total # of Subjects to be enrolled:		
PI:	Contact:	Study recruiter:
PI phone:	Contact phone:	Recruiter phone:
PI email:	Contact email:	Recruiter email:
Project period:		

2. Sites		
All sites used during protocol	<input type="checkbox"/> All HCSD facilities	<input type="checkbox"/> LJCMC
	<input type="checkbox"/> EKLMC	<input type="checkbox"/> HOP
	<input type="checkbox"/> LSU Interim Hospital – New Orleans	<input type="checkbox"/> GCRC
	<input type="checkbox"/> BMC	<input type="checkbox"/> CRONO
	<input type="checkbox"/> LAK	<input type="checkbox"/> OTHER:
	<input type="checkbox"/> WOMRMC	
	<input type="checkbox"/> UMC	
<input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient		Clinics involved:

3. Non Applicable Billing Status	
If this research project meets one or more criteria in this section AND does not include any additional tests, procedures, or visits, complete the following section. You do not need to complete the rest of the billing plan form. Please sign and date the attestation at the end of the form.	
<input type="checkbox"/> Database or patient registry	<input type="checkbox"/> Retrospective study
<input type="checkbox"/> Questionnaire or survey	<input type="checkbox"/> Tissue sample/analysis (discarded tissue samples or blood collection by the PI for internal processing not utilizing a hospital lab)
<input type="checkbox"/> Interviews	<input type="checkbox"/> Long-term follow-up (active treatment complete, no tests or
<input type="checkbox"/> Chart Review	<input type="checkbox"/> Data analysis only
<input type="checkbox"/> Educational, Training, or Other Program	<input type="checkbox"/> IRB renewal (Billing Plan already on file)
<input type="checkbox"/> Recruitment/Referral Center Only	<input type="checkbox"/> Other: (specify)

4. Coverage Analysis		
Is this a "qualifying trial" under the National Coverage Decision? http://www.cms.hhs.gov/clinicaltrialpolicies/		
<input type="checkbox"/> YES	Meets all the following criteria:	
	<input type="checkbox"/> Evaluates a Medicare Benefit	<input type="checkbox"/> funded by governmental agency (NIH, NCI, etc.) or supported centers or cooperative groups funded by a governmental agency AND/OR <input type="checkbox"/> Conducted under an IND or exempt from an IND # _____
	<input type="checkbox"/> Has a therapeutic intent	
	<input type="checkbox"/> Enrolls diagnosed beneficiaries AND	
<input type="checkbox"/> NO		

5. Financial Information	
According to the consent form, who is responsible for payment for tests, procedures, and/or treatment related to this study? (mark all that apply)	
<input type="checkbox"/> Sponsor <input type="checkbox"/> Third Party Payer <input type="checkbox"/> Subject	
Externally Funded via:	Name and Address of Guarantor
<input type="checkbox"/> federal grant, specify agency and grant award #:	
<input type="checkbox"/> industry contract; specify company:	
<input type="checkbox"/> cooperative groups; specify: _____	
<input type="checkbox"/> foundation grant:	
<input type="checkbox"/> other:	

6. Drug and Device Analysis.	
Important: Attach any documentation regarding coverage for this study from the FDA, Sponsor, Medicare, or other third party insurers.	
<input type="checkbox"/> This is not a drug/device study (please skip to next section)	
<input type="checkbox"/> Device Study	Name of Device:
	<input type="checkbox"/> FDA approved for population and indication
	<input type="checkbox"/> Off label use (FDA approved)
	<input type="checkbox"/> IDE – Category B <input type="checkbox"/> IDE-Category A <input type="checkbox"/> NA
	<input type="checkbox"/> Local Medicare Intermediary has been contacted and appropriate payment information has been received (please attach Medicare letter)
<input type="checkbox"/> Drug Study	Name of Drug:
	Provided by:
	<input type="checkbox"/> FDA approved for indication and population
	<input type="checkbox"/> Off label use (FDA approved)
	<input type="checkbox"/> Investigational in population
<input type="checkbox"/> Investigational in indication	

	Name of Drug:
	Provided by:
	<input type="checkbox"/> FDA approved for indication and population
	<input type="checkbox"/> Off label use (FDA approved)
	<input type="checkbox"/> Investigational in population
<input type="checkbox"/> Investigational in indication	

