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

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Deputy Chief Executive Officer
LSU Health Care Services Division

6/12/17
Date

Chief Medical Officer
LSU Health Care Services Division

6-12-17
Date

## I. Purpose and Scope:

The purpose of this policy is to establish uniform minimum requirements and conditions in which a Louisiana State University Heath Care Services Division (HCSD) hospital is authorized to participate in any sponsored project or to conduct research as a clinical research performance site. It establishes policies for professional and technical services provided as part of HCSD based clinical research at all sites of practice regardless of source of funding,

This policy applies to HCSD Headquarters and all HCSD hospitals, employees and medical staff/faculty regardless of medical school affiliation (LSU, Tulane and Ochsner faculty, etc.) who conduct research, quality improvement projects in HSCD hospitals.

## II. Policy Statement:

**A.** It is the policy of HCSD that any program whose employees receive any part of their salary through HCSD, or whose activities use any HCSD resources or facilities (staff time, file space, clinic use, supplies, equipment, computer use, etc.) shall submit all proposals for externally supported projects to the HCSD Chief Medical Officer, Deputy Chief Executive Officer, or Chief Executive Officer (HCSD approver), and shall receive approval from the Hospital CEO prior to any such activity conducted.

Such activity, hereafter collectively referred to as "Sponsored Projects," include, but are not limited to:

1. grants
2. sub-grants
3. clinical trials
4. clinical research
5. health services research
6. data collection for non-HCSD entities or persons
7. Other project activities other than "fee for service" activities authorized by:
    - i. interagency transfers
    - ii. agreements
    - iii. contracts
    - iv. memorandums of understanding
    - v. sponsored endeavors
    - vi. cooperative endeavors

Hospital CEO approval and HCSD coordination of all sponsored projects is necessary to ensure that:

1. All research conducted at an HCSD facility is legally, ethically and financially sound.
2. Billing for costs incurred in the conduct of clinical studies using HCSD resources occur only as appropriate and in compliance with relevant laws, regulations, LSU CM 35 and CM 21.
3. All charges and requests for payments are unduplicated and allowable under related laws, regulations and policies.
4. All projects comply with applicable law, regulations and policies of the State of Louisiana and federal government.
5. All provide the necessary information, documentation, etc., for accurate reporting.

B. Prior to engaging in any research, HCSD hospitals must ensure, by using an interdisciplinary approach, the following conditions are met:

**A.** The research is consistent to the mission of the hospital and will benefit the patients of the hospital.
**B.** All project activities and documentation are thoroughly reviewed particularly the Research Protocol, Clinical Trial/Clinical Research Agreement, and the Informed Consent.(if applicable)
**C.** The project has Institutional Review Board (IRB) approval and is reviewed annually for approval from LSUHSC-NO pursuant to CM 35 and CM21and if conducted by a HCSD employee.
**D.** Charges for "routine care" as defined by Medicare are outlined in the treatment protocol and consent form.
**E.** Costs associated with the protocol are analyzed to determine what is paid/reimbursed by the sponsor.
**F.** A cost analysis outlining which costs will be reimbursed by the trial sponsor or third party provider (including free care if applicable) is completed. The cost analysis must include all HCSD resources (staff, space, equipment, supplies, indirect costs, etc.) that will be used to support the trial.
**G.** Negotiation with the sponsor is conducted to cover project costs.
**H.** A determination of whether the project or clinical trial/clinical research is worthy of participation based on several factors such as mission, revenue/cost ratio, benefits to patients served by the organization and ability to recruit patients is made by the HCSD approver.
**I.** Review processes to evaluate project compliance, with particular emphasis on billing practices, is in place.
**J.** Procedures for appropriate billing are in place.
**K.** All study staff/recruiters have documentation of HIPAA/CITI training specific to research.
**L.** All hospital departments that will be affected by the sponsored project/clinical trial, including clinics, are informed of the proposed study.

## III. Procedure

The HCSD hospital that participates in any sponsored project/clinical trial shall develop and implement procedures in which the clinical, compliance issues and processes related to such activities are addressed. These procedures shall include:

The HCSD Chief Medical Officer, Deputy Chief Executive Officer, or Chief Executive Officer (HCSD approver) receives all of the necessary information from the Principal Investigator (PI) to establish compliant processes prior to the commencement of studies involving HCSD data and/or patients. This formal performance site approval process shall include:

1. Submission by the PI of all research documents to the HCSD approver (with or without IRB approval). These documents will be reviewed by the HCSD approver to comply with all local, state and federal regulations.
2. Review of the research protocol, clinical trial/clinical research agreement (if applicable) and informed consent for consistency. These documents must not conflict. Inconsistencies can lead to inappropriate billing.

3. Review and identification of Institutional Review Board (IRB) requirements as outlined in the current established IRB and FWA policies.
4. Verification of a HCSD Billing Plan.
5. Review of the research study to determine if the facility should agree to be a performance site based on the hospital's mission, the cost factors involved and benefit to the patient population.
6. Once approved by the HCSD approver, a letter of site approval will be sent to the PI that will state the conditions of approval. This approval letter must be presented to all parties involved, particular clinics; prior to subject recruitment; prior to submission to biostatisticians when requesting patient data, medical records, reviewing charts as part of a protocol and prior to submission to information technology statisticians when requesting access to databases.
7. Determine and ensure a mechanism in which the ownership of research data remains the property of HCSD.

**B. Federally Funded Research Projects**

All federally funded research projects shall be processed through LSUHSC and shall be coordinated through the HCSD approver.

**C. Resources**

The HCSD approver is a resource for researchers and staff to whom this policy applies. The approver also acts as a liaison between investigators and other offices on grant or contract-related matters included but not limited to maintaining a database of studies that are being conducted within HCSD facilities, maintaining paper and/or electronic files for each study, managing data use agreements, reviewing manuscripts prior to submission and so forth.

**D. Records Management Requirements**

Under the HIPAA Privacy rule, compliance is considered a healthcare operation function. Therefore, compliance officers at HCSD and each site of practice will have access to the following records for auditing purposes:

The PI or designee shall maintain records related to research studies and make such records available upon request from the HCSD compliance, legal counsel, and/or practice site compliance officer:

All documents associated with clinical trials, including medical records, must adhere to the LSU-HCSD Record Retention Policy # 0516-15.

**E. Documentation in the Medical Record.** The principal investigator will ensure the medical record includes: trial name, sponsor, and sponsor assigned protocol number, by placing a copy of the informed consent document in the medical record, unless a waiver of consent of documentation was granted by the IRB.

## F. Audit & Compliance Requirements

1. All records related to Sponsored Projects and/or Research must be made available to any authorized State, Federal or LSU HCSD auditor.
2. The Compliance Office at each and/or the respective site will perform periodic random compliance audits of clinical research involving patient care costs to ensure compliance with this policy and the applicable billing rules.

## 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