

Date: April 21, 2004

To: HCSD Medical Directors and Hospital Administrators

Fr: John Rock, M.D., Chancellor
LSU Health Sciences Center – New Orleans

Robert M. Plaisance, Interim CEO
Health Care Services Division

Re: Policies and Procedures on Clinical Trials

The LSU Health Sciences Center and Health Care Services Division are committed to the pursuit of quality clinical trials research in our facilities, which increase our capability to provide quality patient care. Such research should ultimately contribute to progressive medical science and enhanced patient care. The integrity of that research is critical to LSU to ensure future research resources.

The purpose of this memorandum is to address four specific issues related to clinical trials. First, based on an initial survey in 2002 by the LSU HCSD Compliance Officers, it appears that generally, hospital staff is unfamiliar with policies, procedures and regulations governing the LSU HSC – NO Institutional Review Board (LSU IRB) Violation of the proper processes set forth by the LSU HSC – NO IRB could result in needless liability imposed upon the university and a loss of future research dollars. It is imperative that proper approval be secured from LSU HSC – NO. We have attached the LSUHSC – NO IRB Policies and Procedures to this document for your review. If IRB approval for research conducted in the HCSD medical centers is secured from another accredited IRB such as Tulane University, Ochsner, etc., the signed approval form must be forwarded to the LSU HSC IRB. It should be noted that in accordance with federal regulations, the IRB of record is the IRB of the employee. Therefore, an LSUHSC employee as the principal investigator is subject to the LSUHSC – NO IRB. For additional information and required forms, please access the LSU HSC – NO IRB web site at <http://www.lsuohsc.edu/no/Administration/rs/irb>. Additionally, you may contact Mike Butler, M.D., HCSD's Chief Medical Officer at 225-922-0796 or mbutle1@lsuohsc.edu.

There is an established research committee at MCLNO which addresses the clinical and compliance issues and processes related to clinical trials. We urge you to set up a similar committee at each of your facilities to provide checks and balances that will ensure compliance in securing and conducting clinical trials.

Secondly, as clinical trials expand in HCSD medical centers, it is critical to ensure that proper research protocols are being followed. The development and expansion of Disease Management has led to the opportunity for all HCSD hospitals to participate in formal clinical trials. These opportunities will only grow as HCSD is better able to manage and collect data on populations in care system-wide. However, with these expansions, clinicians with minimal prior research experience will be participating in research studies. If not conducted with the appropriate diligence to meet monitoring standards, not only could current sponsored project dollars have to be refunded, but future opportunities may be lost. Over time, these lost opportunities could have an impact of hundreds of thousands or even millions of dollars.

Thirdly, there are third party reimbursement issues pertaining to clinical trial agreements within HCSD medical centers which merit attention. In order to receive third party cost reimbursement for the costs which are *allowable*, the clinical trial must be eligible according to Federal regulations. In short, the clinical trial must meet specific criteria, including scientific support, credible and capable sponsorship and protection of participating patients.

You should become familiar with the requirements defined by the Centers for Medicaid and Medicare. There are critical distinctions defining allowable and unallowable cost reimbursement for expenses related to clinical trials.

A hospital CANNOT bill or receive cost reimbursement from third parties for:

- Items and services which are being reimbursed through clinical trial agreements.
- Items and services provided solely to satisfy the data collection needs of the clinical trial.
- The investigational intervention being tested.
- Anything being provided free by the sponsor of the trial to the hospital and/or the patient.

A hospital CAN bill or receive cost reimbursement from third parties for:

- Items and services that would otherwise be covered by Medicare if they were not provided in the context of the clinical trial.
- Items and services “required solely for the provision of the investigation item or services.” For example, Medicare will pay for the *administration* of a chemotherapy drug that is being tested in a trial, including the provision of anti-nausea drugs to prevent complications from the chemotherapy drug.
- Monitoring and evaluation, device implementation, and other costs such as room and board as part of a hospital stay required as part of the clinical trial, for trials of importance to Medicare beneficiaries.

For more detailed information regarding reimbursement for clinical trials, please refer to the following web sites. The Centers for Medicaid and Medicare Services (CMS) clinical trials web site is <http://cms.hhs.gov/coverage/8d.asp> and the specific site within for information on qualifying and coding is <http://cms.hhs.gov/coverage/8d3.asp> .

To review CMS's Final National Coverage Decision bulletin on clinical trials go to <http://cms.hhs.gov/coverage/8d2.asp> . The CMS Clinical Trial website for the CMS Fact Sheet issued 9/19/2000 is <http://www.cms.hhs.gov/medlearn/refctmed.asp> .

Finally, we would like to request an inventory of all clinical trials currently underway in your respective medical centers. Attached is the inventory template. In order to expedite that process, please request the electronic inventory template from Marcia Daigle, HCSD Planning Director, at mdaigle@lsuhsc.edu. Upon returning the completed inventory, please also forward by mail, copies of the applicable signed LSU IRB approval forms for each study.

In closing, we wish to thank you for your continued valuable contribution to the LSU Health Sciences Center – Health Care Services Division. We trust you appreciate the critical nature of our request and will see that all is in order immediately.

Attachments

cc: Dr. Joseph Moerschbacher
Dr. Kenneth Kratz
Dr. Joe Delcarpio