

# OFFICE OF RESEARCH ADMINISTRATIVE DIRECTIVE

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## External Clinical Research Monitoring Visits

### A. PURPOSE

To describe the policies and procedures for the LSUHSC-S Clinical Trials Office with respect to monitoring by external agencies [i.e., pharmaceutical companies, study sponsors, Contract Research Organizations (CROs), etc] for clinical research approved at the LSUHSC-S.

### B. POLICY

Investigator records (i.e., regulatory documents, case report forms, correspondence, study files, etc.) and subject's medical records [i.e., source documents, Computerized Patient Records System, informed consent documents, etc.] are subject to inspection and monitoring by external agencies [i.e., pharmaceutical companies, study sponsors, Contract Research Organizations (CROs), etc.]. These site visits may be routine or conducted for specific causes. In accordance with the facilities Human Subjects Protection Program (HRPP) any findings or issues of concern resulting from a monitoring visit must be forwarded to the Clinical Trials Office to assure that they are appropriately addressed and to notify the appropriate facility officials and committees. The LSUHSC-S Clinical Trials Office will also utilize the monitor visit to meet with the external monitors to discuss new studies and research opportunities for LSUHSC-S.

### C. ACTIONS:

#### 1. Notice of a monitoring visit

The Assistant to the Director of the Clinical Trials Office is to be notified of all monitoring visits by external monitoring agencies as soon as possible. This is the responsibility of the research staff person who schedules and/or confirms the monitoring visit. Notification should be by email to [smandi@lsuhsc.edu](mailto:smandi@lsuhsc.edu) or by registering the visit at the following web site <http://mcsweb.lsuhs-c-s.edu/RepRegistration/Register.asp> (Appendix IV). If the monitoring visit is unscheduled, the Clinical Trials Office is to be notified as soon as the study personnel are aware of the visit. This may be done by telephone at 318-813-2055.

## 2. At the time of the monitoring visit

The CRO or Sponsor study monitor must sign in as a visitor by calling 318-675-2057 (leave message if no answer). A Research Monitor Log will be maintained by the Clinical Trials Office using the form listed below, which will collect the following information:

Name	Destination	Date	Time In	Expected Time Out	Remarks (badge #)
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## 3. Visitor badges will be issued by the Department

The Research Monitor Visitor badge must be worn at all times (supplied by CTO to all departments; see Appendix I). Monitors assigned a Research Monitor Visitor badge must be accompanied by a LSUHSC employee at all times when not in the designated monitoring area.

## 4. Non-compliance findings

The PI or designated site study staff must inform the monitor that any potential or actual serious findings must be conveyed to the Investigator and to the Director of the Clinical Trials Office or his designee during an exit interview or via phone. Findings that require an exit interview include but are not limited to:

1. Any suspicions or concerns that serious non-compliance may exist
2. All findings of serious non-compliance with study protocol, Institutional Review Board (IRB) requirements or applicable regulations and policies (i.e., failure to consent subjects, entering subjects who do not meet inclusion criteria for protocols, failure to report serious or unexpected adverse events).
3. Monitoring visits conducted by a regulatory agency (FDA, NIH, OHRP)

## D. LSUHSC-S External Monitor Agreement form

The CRO or study monitor must provide a signed LSUHSC-S External Monitor Agreement form (Appendix II) to the Clinical Trials Office prior to initiation of any site visit or during the first site visit.

1. During the monitoring activities, the external monitor may only access information and research data that is necessary and in accordance with the approved protocol.
2. The external monitor may not review data in the electronic medical record except under the direct supervision of the LSUHSC-S research staff.
3. A copy of this form will be kept in the CTO and by the Research Department.

## E. LSUHSC-S Report of Clinical Research Monitoring Visit

The CRO or study monitor will complete and sign the "LSUHSC-S Report of Clinical Research Monitoring Visit" form (Appendix III). Completion of this form is required independent of the findings associated with the visit. A copy of this form will be kept in the CTO and sent to the IRB office.

## **F. Following the Monitoring Visit**

1. The PI or designated study staff must forward (fax 318-318-2058) all completed "LSUHSC Report of Clinical Research Monitoring Visit" forms to the Clinical Trials Office.
2. All monitoring reports with potential or actual serious findings will be evaluated by the appropriate LSUHSC-S staff to implement changes or education as needed. These reports must be forwarded to the Human Research Protection Program (*HRPP*) QA staff for review and recommendations.
3. All monitoring reports with potential or actual serious findings will be forwarded to the Human Research Protection Program (*HRPP*) and will be included at the time of IRB continuing review for the protocol.
4. The Principle Investigator and/or Coordinator have the right to appeal, correct, or make recommendations based on the Monitor's statement. This should be completed upon LSUHSC-S letterhead and will become part of the Monitor Visit Report.
5. This is an LSUHSC-S internal document and does not have to be filed in the Sponsor's Regulatory Binder unless requested to do so by the LSUHSC-S Human Research Protection Program. However, you should keep all copies of these reports in a separate file.

Appendix I

**VISITOR  
CLINICAL  
RESEARCH  
SPONSOR  
REPRESENTATIVE**

CONTACT THE CLINICAL  
TRIALS OFFICE FOR  
INFORMATION  
813-2055

**ID # 0001**

**LSUHSC-S**

**Clinical Trials Office**  
LSU HEALTH SCIENCES CENTER SHREVEPORT

**LSUHSC External Monitor Agreement Form**

All external monitors reporting to LSUHSC-S must follow all relevant LSUHSC-S policies and procedures while visiting.

This External Monitor Agreement Form must be signed and returned to the LSUHSC Clinical Trials Office prior to initiation of monitoring visit.

All external monitors must sign in as a visitor at the LSUHSC Clinical Trials Office by calling 318-813-2055 and receive a visitor's badge from a research site representative.

External monitors may only access research data and protected health information that is necessary and in accordance with the approved protocol.

External monitors are not allowed unsupervised access to the electronic medical record or to any other non-research records that contain identifiable protected health information (PHI).

Any potential or actual serious finding must be conveyed to the investigator and the Director of the Clinical Trials Office or his representative during an exit interview at the time of the monitoring visit.

External monitors must complete the "LSUHSC-S Report of Clinical Research Monitoring Visit" form prior to departure from the facility.

A written follow up reported is required for any potential or actual serious findings and must be forwarded to the principal investigator and the LSUHSC-S Clinical Trials Office.

Signature of Monitor: \_\_\_\_\_

Date: \_\_\_\_\_

Printed Name: \_\_\_\_\_

Title of Monitor: \_\_\_\_\_

Company Name: \_\_\_\_\_

Study Name: \_\_\_\_\_

IRB Number: \_\_\_\_\_

Witness: \_\_\_\_\_

**Please keep a copy for your records and Fax to the CTO at 318-813-2058**



**LSUHSC-S Report of Clinical Research Monitoring Visit**

Date: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Study Name: \_\_\_\_\_ IRB # \_\_\_\_\_

Was this visit-pre arranged? \_\_\_NO \_\_\_YES

Auditor(s): \_\_\_\_\_

Company: \_\_\_\_\_

Sponsor: \_\_\_\_\_

Regulatory Agency:  N/A \_\_\_\_\_

Reason for visit: Initiation Visit    Routine / Periodic Monitoring Visit    For Cause Visit    Close-Out Visit  
Other: \_\_\_\_\_

**Check all that apply:**

- Results of this monitoring visit are satisfactory; no concerns of serious non-compliance  
Complete form and return to Study Coordinator with visitors' badge
- Results of this monitoring visit found suspicions or concerns of serious non-compliance  
Highlight your findings below and contact the Clinical Trials Office (CTO) to schedule an exit interview with the CTO Director at 318-813-2055 or 318-813-2057
- This was a Regulatory Agency Visit (FDA, NIH, OHRP)  
Contact the Clinical Trials Office (CTO) to schedule an exit interview with the CTO Director at 318-813-2055 or 318-813-2057

If applicable, findings associated with suspicions or concerns of serious non-compliance\*:

\*If suspensions or concerns of serious non-compliance are identified a follow up report must be immediately carbon copied to the Clinical Trials Office (CTO) at 318-813-2058 (fax).

Signature of Monitor: \_\_\_\_\_

Printed Name and Title of Monitor: \_\_\_\_\_

Monitor's Contact Information: \_\_\_\_\_

Do you have an anticipated date of next visit? \_\_\_NO \_\_\_YES, if yes date \_\_\_\_\_

APPENDIX IV

Online at ( <http://mcsweb.lsuhs-c.edu/RepRegistration/Register.asp> )

## Clinical Trials Office

LSU HEALTH SCIENCES CENTER SHREVEPORT


### SPONSOR'S REPRESENTATIVE REGISTRATION

Please register **all** Monitor visits including pre-study, initiation, routine and inspections

	Short Study Name
	IRB Number
	Investigator's Name
	Coordinator's Name
	Coordinator's Phone Number
	Monitor's Name
	Arrival Date
	Departure Date
	Building/Room where Monitor will be placed
	First time this monitor has been to LSUHSC-S?
	Reason for visit

All monitors must sign the LSUHSC External Monitor Agreement Form during their first visit.  
If you need a copy of the Monitor SOP which contains the LSUHSC External Monitor Agreement Form  
please click here. <http://mcsweb.lsuhs-c.edu/RepRegistration/Register.asp>

Signature Approval:



Sandra C Roerig, Ph.D

Dean, School of Graduate Studies

Associate Dean for Research

Professor, Department of Pharmacology, Toxicology & Neuroscience



Robert A. Barish, MD, MBA

Chancellor, Louisiana State University Health Sciences Center - Shreveport

Wednesday, June 10, 2009

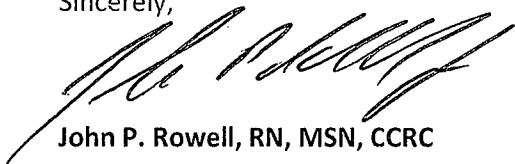
Subject: External Clinical Research Monitoring Visits

The Office of Research, through the Clinical Trials Office, is continuously trying to improve the methods of clinical research for the LSUHSC-S Investigators. In review of some research processes, we realized LSUHSC-S was insufficiently following the external Sponsor Representatives (Monitors) for clinical research. Therefore, the Clinical Trials Office developed a process to track and meet with the External Sponsor Representatives. The attached Administrative Directive was developed for the following reasons:

1. External Sponsor Representatives (Monitors) do not register when they visit the Institution. This means that only the person(s) they visit are aware they are on the LSUHSC-S campus. This could pose a safety and possibly a confidentiality problem.
2. Many times Monitors find problems at the site that could be resolved or should be addressed before they leave the site. Waiting for the monitoring follow-up letter to review problems causes additional problems as it takes 2 – 3 weeks to get these from the Sponsor. With the inexperience of some research coordinators, compliance issues often go unattended without the Investigators knowledge.
3. The Clinical Trials Office is responsible for marketing the Institution for new research opportunities and the External Sponsor Representatives are an enormous resource for this. By meeting the External Sponsor Representatives as often as possible the Clinical Trials Office can build a network of contacts to increase research at LSUHSC-S.

This Administrative Directive is a continuing process and shall be updated as needed and reviewed at least once a year.

Sincerely,



**John P. Rowell, RN, MSN, CCRC**

Director, Clinical Trials Office

Louisiana State University Health Sciences Center

## MONITOR VISIT SEQUENCE OF EVENTS

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Study coordinator adds the monitor visit to database  
<http://mcsweb.lsuhs-c.edu/RepRegistration/Register.asp>

When monitor arrives at LSUHSC-S she/he is registered either via the website or by calling 318-813-2057. The monitor is given a name badge and reporting sheet by the coordinator.

A daily report is given to the CTO representative listing which monitors are in house and where they are located.

A CTO representative will visit with the Monitor while they are on campus to discuss positive and negative study issues and inquire about future studies. If major subject safety issues are discovered the HRPP will be immediately notified by the CTO representative.

At the end of the monitoring visit, the study coordinator or monitor will fax the Visit Reporting Sheet to 318-813-2058 and it will be:

1. Scanned and placed on a secure web site under the IRB Number for the study. HRPP will have Web site access.
2. A copy will be sent to the PI and Coordinator
3. If major subject safety issues or non-compliance is documented the HRPP will be notified immediately.