LOUISIANA EMERGENCY RESPONSE NETWORK
REGISTRY DATA REQUEST POLICY

INTRODUCTION

The purpose of the registry is to help improve the quality of care of trauma patients or patients with time sensitive illness in the state and to facilitate appropriate system development. The purpose of this document is (1) to define the procedures by which interested parties can gain access to the data in the registry and (2) to outline a process to assure that any publication derived from the registry is a high quality report such that the data are accurately presented, not prejudicial to any person, nor in violation to the confidentiality of any person, EMS agency or hospital.

ETHICAL STANDARDS

Successful applicants who intend to use material obtained from the Louisiana Trauma Registry (LTR) or Louisiana EMS Registry have the responsibility to seek honestly and promulgate ethically the truth in all phases of work. This responsibility extends to all phases of research and creative activities which may result from data obtained from the registries. The Louisiana Emergency Response Network (LERN) has one review committee (the Research Review Committee) that oversees the development of scientific project applications, abstracts, manuscripts or presentations derived from registry data. The committee subscribes to the following principles in considering research and creative activities:

1) Scientific integrity will be inherent in all anticipated activity.
2) Fabrication and falsification of information that an applicant claims is based on registry data is unethical.
3) Intentional selection or treatment of data to present views known by the applicant to be false is unethical.
4) Dissemination of tangible information under the applicant's name which is derived from data from another individual's work without due credit will be considered plagiarism.
5) Observations must be recorded in a manner such that individual institutions and human subjects cannot be identified, either directly or through inference.
6) Observations should be recorded in a manner such that conclusions cannot be judged as prejudicial to any institution or individual.

THE PROCESS TO OBTAIN AND PUBLISH DATA

When straight facts (e.g., for bench-marking or policy-making purposes) are required from the registry, necessitating no interpretation of data, this is considered a Routine Data Request. A request for data requiring or leading to any interpretation or extensive analysis, (e.g., for the testing of hypotheses or from which conclusions will be drawn) is considered a Scientific Data Request. Refer to the Louisiana Hospital Trauma Registry Data Dictionary at http://lern.la.gov/trauma-registry/trauma-registry to determine data points available for analysis. The Chairman of the Research Review Committee will determine if a data request necessitates the review of the research review committee and has the authority to declare a request “minimal risk” and thus authorize the release of

the information. IF there is any question on whether the data represents a minimal risk, the research review committee will evaluate the request and make a determination.

Routine Data Request*:*

For a routine data request, the individual must submit (by mail or email) a completed "Routine Data Request" form (Attachment A) to:

The Louisiana Emergency Response Network
Attn: Chris Hector, Administrative Director
14141 Airline Highway, Suite B, Building 1
Baton Rouge, LA 70817

Whenever possible, LERN should respond to all such requests within ten working days.

Scientific Data Request:

Any scientific data request must identify a principal investigator and must have a Sponsor. The sponsor may serve as a principal investigator for his own data request or oversee the application for data by other parties.
Sponsors have the responsibility for:

1) facilitating the application process;
2) evaluating all applications for access to LERN Trauma or EMS registry data;
3) serving as liaisons between principal investigators and the Louisiana Trauma or EMS registry for each project application;
4) helping to ensure project quality from submission to completion;
5) working to ensure the appropriate use of any Louisiana Trauma or EMS registry data; and
6) assisting investigators in identification of potential strengths and weaknesses of the Louisiana Trauma or EMS Registry data.

No data which risks the breach of patient or hospital confidentiality will be made available to any investigator.

A "Scientific Data Request" form (Attachment B) is to be completed for each scientific data request. The application must be typed and include all required information. The application must include the sponsor's and principal investigator's signatures, verifying they will abide by all publication policies. All Scientific Data Requests must be approved by an Institutional Review Board (IRB).

An electronic copy of the completed forms must be emailed to the LERN Administrative Director, Chris Hector at Chris.Hector@La.Gov. **The LERN will be unable to process applications missing any required information or signatures.**

The LERN will immediately distribute the document via email to the Research Review Committee. The Research Review Committee will have **45** calendar days from the date of request to render a decision.

If there is no disapproval vote by any reviewer, the LERN will advise, in writing, the principal investigator of the approval as well as any comments from reviewers. LERN will coordinate with the principal investigator to arrange for the transfer of the requested information, pending approval by the IRB. With

rare exception, only investigators from hospitals that routinely submit data to the Louisiana Trauma Registry or EMS agencies that routinely submit data to the Louisiana EMS Registry may obtain electronic records (versus aggregate data) for approved research purposes. Exceptions must be approved by the LERN Research Review Committee.

If there is a single disapproval, the LERN will inform the investigator of the denial and objections. The applicant then has three options:

1) to forego the request;
2) to change the request to satisfy the objections and resubmit; or
3) to appeal the decision.

To appeal, the investigator should send an electronic copy of his response to the LERN who will distribute the information to the Registry Research Committee who will respond in writing within **twenty** working days. A majority vote of the reviewers is required to over-rule the initial denial for data.

Normally no charge is assessed for data unless the request is extensive. If the request is extensive, the investigator will be notified of charges beforehand. If the research is funded, then LERN will require reasonable reimbursement to the LERN for all or a portion of the costs of obtaining the data based on the scope of the data request and the level of funding.

Abstracts, Manuscripts or Presentations:

No publication or major presentation shall be made by any party regarding the results of any data analysis without going through the appropriate approval processes, outlined below. **The approval process for abstracts, manuscripts, and presentations is independent of the approval process for the data request.**

Prior to release of any registry data (examples not limited to the form of an abstract, manuscript, or presentation) to any audience, approval must be obtained from the Research Review Committee. An electronic copy of a proposed abstract, manuscript, or presentation, to include the required "Publication Request" form (Attachment C), must be submitted to LERN (Attention: Chris Hector, LERN Administrative Director. Chris.Hector@LA.Gov). These applications will be disseminated to the Research Review Committee. Applicants may be required to present the abstract, manuscript, or presentation to the Research Review Committee. All publications must acknowledge the LERN State Board and the LERN registry.

The Committee will have twenty working days (for abstracts) and forty five working days (for manuscripts and presentations) to forward an approval/disapproval by email or in writing (delineating concerns) to the LERN. Any disapproval shall be simultaneously copied to the Chair of the Research Review Committee who will work with his Committee, with its specific expertise, to render a final approval or disapproval through the LERN. Committee disapproval will delineate the concerns as well as the constructive criticisms. The author may then:

1) forego the work,
2) rewrite the abstract, manuscript, or presentation and resubmit it through normal channels, or
3) follow the appeals process.

In the appeals process, the author must send the Administrative Director at LERN an electronic copy of the abstract, manuscript, or presentation with a response to the Research Review Committee's

concerns. The LERN shall email the notice of appeal and corresponding materials to the Research Review Committee, giving them fifteen working days to forward an approval or disapproval to the LERN. If the majority of the Research Review Committee approves the document, it is approved. However, all committee members must respond and there will NOT be a default mechanism whereby the failure to respond is considered a favorable reply. In the event of a split vote, the Chairman of the Board shall cast the deciding vote.

RESEARCH REVIEW COMMITTEE APPOINTMENT PROCESS

A Research Review Committee will be appointed by the Chairman of the LERN Board in January of every even year, to consist of at a minimum the Vice Chairman, who serves as chairman of the committee and 3 LERN State Board members. There must be one trauma program medical director or one trauma surgeon, one EMS representative, one member from the general board , and at least one LERN staff member who is not a voting member. If for any reason a member's board term is concluded prior to the time for the next appointment or cannot serve, the member may be replaced at the discretion of the Chairman of the LERN Board. Should one member of the Committee have a conflict of interest with the research in question, the Chairman of the Research Review Committee may name a substitute for the review of that one request.

SUMMARY OF STEPS/TIME FRAMES FOR APPROVAL OF TRAUMA REGISTRY RESEARCH

Routine Data (basic facts off the registry):

• Complete a "Routine Data request" form and forward to the Louisiana Emergency Response Network for their response in **ten** working days or less.

Scientific Project Data:

Initial Requests:

• Complete a "Scientific Data Request" form and forward one paper copy (signed) and one electronic copy to the LERN.

• The LERN will immediately distribute the application to the Research Review Committee members who shall have **45** working days to forward an approval/disapproval to the LERN. Failure to communicate an approval/disapproval by the deadline will be construed as approval of the data request. A single disapproval vote means the application will be denied.

Appeals:

• Applicant forwards to the LERN one electronic copy of response to the Research Review Committee concerns.

• The LERN will distribute the response to the Research Review Committee members, giving them **20** working days to render an approval or disapproval to the LERN. If the majority of the Research Review Committee members approve the document, it is approved. However, ALL committee members must respond. In the event of a split vote, the Chair shall cast the deciding vote.

ATTACHMENTS

ATTACHMENT A: Routine Data Request Form

Louisiana Emergency Response Network
14141 Airline Highway Building 1, Suite B
Baton Rouge, LA 70817
(225)756-3440/Fax: (225)756-3429
e-mail: Chris.Hector@La.Gov

Routine Data Request

INDIVIDUAL REQUESTING INFORMATION:

INSTITUTION: DEPARTMENT:

ADDRESS:

PHONE: FAX: EMAIL:

DATE OF REQUEST: DATE NEEDED:

INFORMATION REQUESTED (Refer to the LERN Trauma Registry Data Dictionary or the LERN EMS Registry Data Dictionary at http://lern.la.gov/trauma-registry/trauma-registry to determine data points available for analysis.):

PURPOSE OF INQUIRY:

PREFERRED FORMAT (electronic or hard copy; spreadsheet or report with narrative):

****

LERN USE ONLY

DATE RECEIVED: _____

REQUEST RECEIVED BY: _____

DATE ADDED TO TRACKING SYSTEM: _____

DECISION: APPROVE REQUEST/DENY REQUEST

DATE DECISION COMMUNICATED: _____

PERSON NOTIFIED: _____

ATTACHMENT B: Scientific Data Request Form

SCIENTIFIC DATA REQUEST

APPLICATION FOR DATA

FROM THE LERN TRAUMA/EMS REGISTRY DATABASE

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

TITLE: _____

INSTITUTION: _____

ADDRESS: _____

TELEPHONE: _____

EMAIL ADDRESS: _____

Sponsor/Principal Investigator (PLEASE PRINT):_____

INSTITUTION: _____

NAME OF INSTITUTIONAL REVIEW BOARD: _____

***MUST INCLUDE A COPY OF THE INSTITUTIONAL REVIEW BOARD APPROVAL LETTER ***

WE THE UNDERSIGNED AGREE NOT TO PUBLISH OR PUBLICLY PRESENT DATA PROVIDED FROM THE LOUISIANA EMERGENCY RESPONSE NETWORK TRAUMA REGISTRY OR EMS REGISTRY WITHOUT PRIOR APPROVAL BY THE RESEARCH REVIEW COMMITTEE, AND TO GUARD THE CONFIDENTIALITY OF ANY DATA PROVIDED TO US BY THE LOUISIANA EMERGENCY RESPONSE NETWORK TRAUMA REGISTRY OR EMS REGISTRY.

REQUIRED SIGNATURES:

PRINCIPAL INVESTIGATOR: _____ DATE: _____

SPONSOR: _____ DATE: _____

PLEASE NOTE: Failure to complete all sections will result in form being returned. Refer to the LERN Data Dictionary (http://lern.la.gov/trauma-registry/trauma-registry) to accurately request data points for analysis.

1) PROJECT DESCRIPTION (one sentence):

2) HYPOTHESIS:

3) METHODS (steps involved in project, required analysis):

4) LITERATURE REVIEW (synopsis of key articles, last 5 years):

5) REFERENCES (from literature):

6) SIGNIFICANCE (how this review may contribute to the literature):

7) CO-INVESTIGATORS (include titles/areas of expertise):

8) TIME FRAME OF DATA REQUESTED FROM TO

9) LIST DATA POINTS KNOWN TO BE NEEDED. Refer to the LERN Data Dictionary (http://lern.la.gov/trauma-registry/trauma-registry) to accurately specify data points.

10) LIST SPECIFIC ANALYSES REQUESTED (if not included in Methodology):

11) PREFERRED FORMAT:

□ Electronic database records - for investigator's analysis

□ Aggregate - data analyzed by NCTR personnel

ATTACHMENT C: Publication Request

Louisiana Emergency Response Network

14141 Airline Highway Building 1, Suite B

Baton Rouge, LA 70817

(225)756-3440/Fax: (225)756-3429

e-mail: Chris.Hector@La.Gov

Request for Permission to Publish or Present NCTR Research

Title:

Corresponding Author:

Authors:

Conference/Journal:

Submission Deadline:

Title and Date of Original Scientific Data Request:

** MUST SUBMIT COPY OF ARTICLE/DATE WITH THIS REQUEST

Name/Signature of Requester _____ Date _____