

North Carolina EMS Region I Data Access Procedure
April 2005

INTRODUCTION

The purpose of this document is (1) to define the procedures by which interested parties can gain access to the data in the database and (2) to outline a process to assure that any publication derived from the database 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 or EMS System.

ETHICAL STANDARDS

Successful applicants who intend to use material obtained from the database 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 registry.

Region I has two review committees (the Research Review Committee and the Publications Committee) that oversee the development of scientific project applications, abstracts, manuscripts or presentations derived from database data. They subscribe 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 database 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) Applicants must list co-authors of a work to be disseminated in any form, but only with the co-authors' express consent. The unwarranted inclusion of co-authors who have not been substantially involved in the work is unethical.
- 6) Observations must be recorded in such a manner that individual institutions and human subjects can not be identified, either directly or through inference.
- 7) Observations should be recorded in a manner such that conclusions can not be judged as prejudicial to any institution or individual.

THE PROCEDURE TO ACCESS DATA

Any request for Region I data by an individual (called the "primary investigator") must be made in writing not less than ninety (90) days from the date the data is needed. The primary investigator should submit the proper form, including a description of the data needed, the way data should be returned to them, and a fee of \$100 payable to Council of Governments. A place is available on the application forms to waive the \$100 fee. If for any reason the application is denied, the fee will be returned. However, if data is supplied, the fee will stand regardless of the status of publication(s) from such data. After review of the application as listed below, the Primary Investigator may be contacted by the committee for an interview.

Frivolous, poorly conceived or incomplete applications are unlikely to ever come to meaningful fruition are discouraged.

No data which risks the breach of patient or hospital confidentiality will be made available to any investigator. It is the responsibility of the primary investigator to assure the appropriate use of any data which is obtained from the database and to see that investigators using the data are aware of its potential strengths and weaknesses.

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 PROCESS TO OBTAIN DATA

a. Routine Data:

Often, an individual may require straight facts (e.g., for bench-marking or policy-making purposes) from the database, requiring no interpretation of data. In this case, the individual must submit only a completed "Routine Data Request" form (Attachment A) to the NC EMS Region I Database (Attn: Dr. Jason Edsall, Medical Director, NC EMS Region I, 830 Rockford St., Mt Airy, NC 27030). Whenever possible, Region I should respond to all such requests within thirty(30) days.

b. Scientific Project Data:

A "Scientific Project Application for Data" form is to be completed for each major request for project data. The application must be typed and include all required information, including the signature of the primary investigator, verifying he/she will abide by all publication policies. One electronic copy of the completed form must be emailed to Jason Edsall at jasonedsall@adelphia.net. One

hard copy of the completed form with the required signatures must then be mailed to Jason Edsall (Jason Edsall, Medical Director, NC EMS Region I, 830 Rockford St., Mt Airy, NC 27030, Telephone 336-786-6068). Region I will be unable to process applications missing any required information, signatures or copies. To expedite the approval process, you may fax a copy of the completed form with required signatures to Jason Edsall at 336-789-5495.

Region I will immediately distribute the document to the Research Review Committee. Committee members will be given thirty (30) days to review and approve or disapprove the application in writing.

If there is no disapproval vote by any reviewer, Region I will advise, in writing, both the Region I EMC Advisory Council and the primary investigator of an approval. The investigator will be sent the data as per arrangements requested in application and approved by the committee.

If there is a single disapproval, Region I will inform the investigator of the denial and objections. The objector will not be identified without his/her consent. 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/her response to Region I who will distribute the information to the Region I EMS Advisory Council who will respond to consider the application and appeal at its next regularly scheduled bimonthly meeting. A majority vote of the Region I EMS Advisory Council is required to over-rule the initial denial for data.

c. Abstracts, Manuscripts or Presentations:

An electronic copy of a proposed abstract, manuscript or presentation, to include the required cover sheet (Attachment C), must be submitted to Region I (Attention: Dr. Jason Edsall, Medical Director, jasonedsall@adelphia.net). As with project proposals, these will be disseminated to the Research Review Committee. For presentations, the entire presentation should be forwarded to the Committee.

It is possible, and in fact encouraged, that reviewers give constructive criticism without constituting a denial of the application. The Committee will have thirty (30) working to forward an approval/disapproval (delineating concerns) to Region I. A disapproval will delineate the concerns as well as the constructive criticisms. The author may then forego the work, re-write the paper and resubmit it through normal channels or follow the appeals process.

In the **appeals process**, the primary investigator must send Region I an electronic copy of the abstract, manuscript or presentation to include a response to the Committee's concerns. The North Carolina EMS Region I Advisory Council will consider the application and appeal at its next regularly scheduled bimonthly meeting. If the majority of the North Carolina EMS Region I Advisory Council approves the document, it is approved.

AUTHORSHIP

1) Each author should have participated sufficiently in the work represented by an article to take public responsibility for its content, meaning that any author listed can defend the content of the article including the data and other evidence and the conclusions based on them. "Sufficient participation" should include:

- a) Conception or planning of the project, or at least approval of its design, if enlisted late in the study, or analysis or interpretation of the data (conclusions), or both; and
- b) Participation in writing the article by contributing to drafting or revising it for critically important content; and
- c) Each co-author should read the entire contents of the final version of the paper before it is submitted for publication, and give his/her approval in writing.

2) The lead author should be the person who actually did most of the work and who actively wrote and referenced most of the paper. This lead author will make the final decision as to which authors are included in the final version of the manuscript, the order of authors' names, their roles in the study, as well as where and when to send an abstract or final paper. It is the lead author's responsibility to assure that the listed co-authors are consistent between an abstract and manuscript.

3) After approval of the "Scientific Project Application for Data" by the Research Committee, the lead author should contact each individual who has expressed an interest in participating in the project and the responsibilities of each party should be made clear before work on the project is initiated. Once this is established, the "Scientific Project Application for Data" on file at Region I should be updated to state the role of each participant and a list of the authors' names in tentative order in which they are expected to be listed in the final publication. Any changes in roles or

responsibilities should be openly discussed, with the lead author serving as final arbiter of conflicts.

4) Authorship should not be granted for routine technical help (i.e., contribution of cases, data collection, routine statistical analysis, etc.). Significant contributions not worthy of authorship could be recognized in footnote form or by acknowledgment at the end of the manuscript.

COMPILATION OF RESEARCH

Region I shall receive all requests for project, abstract, and manuscript approvals, processing each in accordance with the policy set forth above. Region I shall also serve as the permanent repository for the research requests and their related approvals, submitting research status reports as requested by the North Carolina Region I EMS Advisory Council.

Copies of the "routine data requests", utilizing the short form, shall also be forwarded routinely to OEMS from Region I in order to ensure a complete compilation of instances when the database data base was utilized.

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

A) **Routine Data** (basic facts off the registry):

Complete a "Routine Data request" form and forward to Region I for their response in thirty days or less.

B) **Scientific Project Data:**

Initial Requests:

Complete a "Scientific Project Application for Data" form and forward one paper copy (signed) and one electronic copy to Region I.

Region I will immediately distribute the application to the Research Review Committee which will have thirty days to forward an approval/disapproval to Primary Investigator. A single disapproval vote means the application will be denied.

Appeals:

Applicant forwards to Region I one electronic copy of response to concerns that served as the basis for disapproval of the project. Region I will immediately distribute the materials to the North Carolina EMS Region I Advisory Council which will consider the application and appeal at its next regularly scheduled bimonthly meeting. A majority vote of the North Carolina EMS Region I Advisory Council is required to over-rule the original denial for data.

C) **Abstracts, Manuscripts or Presentations:**

Initial Requests:

Complete the required cover sheet and email it with the electronic copy of the proposed abstract, manuscript or presentation to Region I. Region I will immediately distribute the document to the Research Review Committee which will have

thirty days to forward an approval/disapproval (delineating concerns) to the Primary Investigator. Any disapproval shall be simultaneously copied to the North Carolina EMS Region I Advisory Council.

Appeals:

If the Committee fails to approve the abstract, manuscript or presentation, the primary investigator can choose to appeal the decision by emailing Region I a response to the Committee's concerns. The North Carolina EMS Region I Advisory Council will consider the application and appeal at its next regularly scheduled bimonthly meeting. If the majority of the North Carolina EMS Region I Advisory Council approves the document, it is approved.

ATTACHMENTS

ATTACHMENT A: Routine Data Request Form

ATTACHMENT B: Scientific Project Application

ATTACHMENT C: Publication Request