



NORTH CAROLINA TRAUMA REGISTRY DATA ACCESS PROCEDURE APRIL 2013

INTRODUCTION

The North Carolina Trauma Registry (NCTR or registry) is a cooperative effort between numerous North Carolina hospitals (including all trauma centers) and the North Carolina Office of Emergency Medical Services (NCOEMS). The purpose of the registry is to house information on all trauma patients and to facilitate trauma system development. Data extracted from the registry is useful to improve the quality of care of trauma patients in the state of North Carolina.

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 is accurately presented, not prejudicial to any person, nor in violation to general statute or the confidentiality of any person or hospital.

The NCOEMS shall receive all requests for project, abstract and manuscript approvals, and process each in accordance with the set policy. The NCOEMS shall also serve as the permanent repository for the research requests and their related approvals, submitted research status reports as requested by the STAC.

ETHICAL STANDARDS

Individuals who intend to use material obtained from the NCTR 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.

The NCTR has a review committee, the Research Review Committee that oversees the development of scientific project applications, abstracts, manuscripts or presentations derived from registry data. They subscribe to the following principles in considering research and creative activities:

1. Scientific integrity will be inherent in all anticipated activities.
2. Fabrication and falsification of information that an applicant claims are 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 application's name which is derived from data from another individual's work without due credit will be considered plagiarism.
5. Individuals must list co-authors of a work to be disseminated in any form, but only after receiving the express consent of the co-author. The unwarranted inclusion of co-authors who have not been substantially involved in the work is unethical.
6. Observations must be recorded in a manner such that individual institutions and human subjects cannot be identified, either directly or through inference.
7. Observations should be recorded in a manner such that conclusions cannot be judged as prejudicial to any institution or individual.

DEFINITIONS

Routine Data Requests – It is considered a routine data request when straight facts necessitating no interpretation of data, for benchmarking or policy-making purposes, are required from the registry.

Scientific Data Request – A scientific data request is a request for data requiring or leading to an interpretation or extensive analysis for the testing of hypotheses or from which conclusions will be drawn.

Research Review Committee – Appointed by the STAC in January of every odd year, this committee consists of the trauma medical directors, the state trauma medical director, two representatives from the Trauma Program Managers Committee, two representatives from the Registrar Committee, the North Carolina Trauma Registry and Disaster Data Analyst, and the NCOEMS Trauma Systems Manager.

AUTHORSHIP

Each author of any abstract, manuscript or presentation (subsequently referred to as “the work”) should have participated sufficiently in the work to take public responsibility for its content. In other words, any author listed can defend the work’s content including the data and other evidence and the conclusions based on them. “Sufficient participation” should include:

1. Conceptualization or planning of the work, and/or analysis and interpretation of the data.
2. Participation in writing the article by contributing to, drafting, or revising it for critically important content.
3. Review and approval of the entire contents of the final work before it is submitted for publication.

With rare exception, authorship should be limited to no more than six individuals per paper. 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 acknowledgement at the end of the manuscript.

The lead author should be the person who actually did most of the work and who actively wrote and referenced most of the papers. This lead author will make the final decision as to which authors are included in the final version of the manuscript, the order of the author's 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 its corresponding manuscript.

The NCOEMS and each individual hospital contributing data to the project shall receive a standard acknowledgement in the final abstract, manuscript or presentation. This shall read as follows, "The authors gratefully acknowledge the efforts of the North Carolina Office of Emergency Medical Services as well as the North Carolina Trauma Registry Hospitals".

Routine Data Request:

For completion of a routine data request, a listing of data points is available at <http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html>

The individual must submit by email, fax or US Postal Service a completed "Routine Data Request" form to Amy Douglas, Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, amy.douglas@dhhs.nc.gov. The NCOEMS should respond to all such requests within 10 working days. This form is available at <http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html>

Scientific Data Request:

For completion of a scientific data request, a listing of data points is available at <http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html>.

Any scientific data request must identify a principal investigator and must be approved by a sponsor, who is the trauma director at a trauma center. In addition to serving as a sponsor for researchers outside his own institution, the sponsor may serve as a

principal investigator for their own data request or oversee the application for data by other members within that institution.

Sponsors have the responsibility for:

1. Facilitating the application process.
2. Evaluating all applications for access to NCTR data.
3. Serving as liaisons between principal investigators and the NCTR for each project application.
4. Helping to ensure project quality from submission to completion.
5. Working to ensure the appropriate use of any NCTR data.
6. Assisting investigators in identification of potential strengths and weaknesses of the NCTR data.

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

A “Scientific Data Request” form is to be completed for each scientific data request. The application must be typed and include all required information along with the principal investigator’s signature, verifying they will abide by all publication policies. All scientific data requests must include an Institutional Review Board (IRB) approval from their institution. One original hard copy of the approval with the required signatures must be mailed to Amy Douglas, Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707. Applicants may be required to present the research design and publication intent to the State Trauma Advisory Committee (STAC). The STAC then may choose to release electronic data to this individual or restrict the data to hard copy only. This form is available at <http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html>.

The NCOEMS will distribute the document within 5 business days, via email, to the Research Review Committee (Attachment D). Committee members will have ten working days to review, comment, and approve or disapprove the applications by email or in writing. Failure to communicate by either email or in writing to the NCOEMS by the deadline shall be construed as approval of the data request.

If there is not a disapproval vote by any reviewer, the NCOEMS will advise, within five business days, in writing, the principal investigator of the approval as well as any comments from the reviewers. With rare exception, only investigators from hospitals that routinely submit data to the NCTR may obtain electronic records (versus aggregate data) for approved research purposes. The NCTR Research Review Committee and the NCOEMS Trauma Systems Manager must approve exceptions.

If there is a single disapproval, the NCOEMS 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 must send an electronic copy of his response to the NCOEMS, Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, who will then distribute the information to the Registry Research Committee. The Registry Research Committee will respond to the NCOEMS, Trauma Systems Manager, in writing within 10 working days. A majority vote of the reviewers is required to overrule 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 externally funded, as through a grant, then consideration should be given to reasonable reimbursement to the NCTR 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 publications or major presentations shall be made by any party regarding the results of any data analysis without going through the appropriate approval processes outline 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, e.g. in the form of an abstract, manuscript, or presentation, to any audience other than the STAC, approval must be obtained from the NCTR Research and Registry Committee. A hard copy with required signatures of a proposed abstract, manuscript, or presentation, to include the required “Publication Request” form (Attachment C), must be submitted to the Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina, 27699-2707. These applications will be disseminated to the Publications Committee (Attachment E).

Reviewers may give constructive criticism without constituting a denial of the application. The committee will have 10 working days for abstracts, and 20 working days for manuscripts and presentations, to forward an approval or disapproval by email or in writing delineating concerns to the Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707. Failure to communicate an approval or disapproval by the deadline shall be construed as an approval. Any disapproval shall be simultaneously copied to the Chair of the Research and Registry Committee, who will work with his committee with its specific expertise, to render a final approval or disapproval through the NCOEMS. 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 Trauma Systems Manager, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707 an electronic copy of the abstract, manuscript, or presentation with a response to the Publications Committee’s concern. The NCOEMS shall email the notice of appeal and corresponding materials to the Research and Registry Committee, giving them 15 working days to forward an approval or disapproval to the Assistant Chief, Health Systems, Office of Emergency Medical Services, Division of Health Service Regulation, 2707 Mail Service Center,

Raleigh, North Carolina, 27699-2707. If the majority of the Publications 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 favorably reply. In the event of a split vote, the Chair shall case the deciding vote.

RESEARCH & REGISTRY COMMITTEE APPOINTMENT PROCESS

A Research and Registry Committee will be appointed by the STAC in January every odd year, and will consist of the trauma medical directors, the state trauma medical director, two representatives from the Trauma Program Managers Committee, two representatives from the Registrar Committee, the North Carolina Trauma Registry and Disaster Data Analyst, the NCOEMS Trauma Systems Manager. Subsequently, the reviewers will select a chairperson.

COMPILATION OF RESEARCH

The NCOEMS shall receive all requests for project, abstract and manuscript approvals, and process each in accordance with the set policy. The NCOEMS shall also serve as the permanent repository for the research requests and their related approvals, submitted research status reports as requested by the STAC.