Introduction
The North Carolina Trauma Registry (NCTR or registry) is a cooperative effort between 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, presentation, 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, and shall submit 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, agencies, 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, agency, 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 requested 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** – This committee is a sub-committee of the STAC, consisting 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 Data Analyst (Sharon Schiro, Sharon_Schiro@med.unc.edu), and the NCOEMS Trauma System Manager (Amy Douglas, Amy.Douglas@dhhs.nc.gov). Membership will be reviewed annually by the constituent committees. The NCCOT Chair shall appoint a Research Review Chair annually.

Rev 10.13, 4.18
**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”.

Rev 10.13, 4.18
**Data Requests**

**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 System 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 and the form are available at http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html.

Any scientific data request must be reviewed by the NC Trauma Data Analyst prior to submission to NC Trauma System Manager. The Trauma Data Analyst will review data requests for appropriate use of NCTR data, as well as consistency between the hypotheses, methodology, and requested data. The Trauma Data Analyst will assist 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. 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 record-level data to this individual or restrict them aggregate data (analytic results) only.
Once the form is submitted to the NC Trauma System Manager, the NCOEMS will distribute the scientific data request within five business days, via email, to the Research Review Committee. Committee members will have ten working days to review, comment, and approve or disapprove the applications by email. Failure to communicate by either email 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 via email within five business days 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 any 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 Amy Douglas, Trauma Systems Manager, Amy.Douglas@dhhs.nc.org, who will then distribute the information to the NCTR Registry Research Committee. The NCTR Registry Research Committee will respond to the NCOEMS Trauma System Manager, by email within ten working days. A majority vote of the reviewers is required to overrule the initial denial for data.

**Fees**

There will be a fee of $60 per hour associated with extracting data for all data requests. Upon submission of the scientific data request to the Trauma Data Analyst, the Trauma Data Analyst will respond within five days with a cost estimate. The final cost of the data request will be the amount of actual work done to extract the data, not
to exceed the original cost estimate. Fees may be waived for STAC member’s research projects that are not grant funded.

**Abstracts, Manuscripts or Presentations**

No submission for 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 Review Committee. The proposed abstract, manuscript, or presentation, and the required “Publication Request” form (http://www.ncdhhs.gov/dhsr/EMS/trauma/traumaregistry.html) must be submitted to the Trauma Systems Manager (Amy.Douglas@dhhs.nc.org). These applications will be disseminated to the NCTR Research Review Committee.

Reviewers may give constructive criticism without constituting a denial of the application. The committee will have ten working days to forward an approval or disapproval by email delineating concerns to Amy Douglas, Trauma System Manager (Amy.Douglas@dhhs.nc.gov). Failure to communicate an approval or disapproval by the deadline shall be construed as an approval. 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 Amy Douglas, Trauma System Manager (Amy.Douglas@dhhs.nc.gov) 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 ten working days to forward an approval or disapproval.
disapproval to Amy Douglas, Trauma System Manager (Amy.Douglas@dhhs.nc.gov). 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 cast the deciding vote.