

NORTH CAROLINA TRAUMA REGISTRY DATA ACCESS PROCEDURE July 2005

INTRODUCTION

The North Carolina Trauma Registry (NCTR or registry) is a cooperative effort between numerous North Carolina hospitals (including all trauma centers) and the Office of Emergency Medical Services (OEMS). The purpose of the registry is to help improve the quality of care of trauma patients in the state and to facilitate appropriate trauma 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 or hospital.

ETHICAL STANDARDS

Successful applicants 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 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 registry 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 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) 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 a manner such 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 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 NCTR Data Dictionary (www.ncems.org/trauma/trauma_registry.htm) to determine datapoints available for analysis. Do not use the forms at the back of this document, as the forms for requesting data or approval to publish data are available on line at www.ncems.org/trauma/trauma_registry.htm.

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 Central Data Collection Agency (CDCA) at UNC (Attn: Dr. Sharon Schiro, Director, North Carolina Trauma Registry, Department of Surgery, CB#7050, University of North Carolina, Chapel Hill, NC 27599-7050). Whenever possible, the CDCA should respond to all such requests within ten working days. A copy of the request and response shall be forwarded simultaneously by the CDCA to the OEMS.

Scientific Data Request:

Any scientific data request must identify a principal investigator and must be approved by a sponsor, the trauma medical director at any trauma center. In addition to serving as a sponsor for researchers outside his own institution, the sponsor may serve as a principal investigator for his own data request or oversee the application for data by other members within his/her 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; and
- 6) assisting investigators in identification of potential strengths and weaknesses of the NCTR data.

Frivolous, poorly conceived or incomplete applications are unlikely to ever come to meaningful fruition and should be discouraged by sponsors. 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 the UNC Institutional Review Board (IRB). The UNC IRB form is available online at <http://ohre.unc.edu/forms.php> and must be submitted with the Scientific Data Request.

One electronic copy of the completed forms must be emailed to the OEMS representative, Sharon Rhyne at Sharon.Rhyne@ncmail.net. One hard copy of the completed forms with the required signatures must be simultaneously mailed or faxed to the OEMS (Attention: Sharon Rhyne, Hospital and Trauma Specialist, Division of Facility Services, 2707 Mail Service Center, Raleigh, North Carolina 27699-2707, Telephone 919-855-3951, Fax 919-733-7021). **The OEMS will be unable to process applications missing any required information or signatures.**

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.

The OEMS will immediately distribute the document via email to the Research Review Committee (Attachment D) which consists of the trauma medical directors, two representatives from the Trauma System Leaders Committee, two representatives from the Registrar Committee, the STAC ISSAC representative, the OEMS Hospital and Trauma Specialist, and the NCTR director. 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 email or in writing to the OEMS by the deadline shall be construed as approval of the data request.

If there is no disapproval vote by any reviewer, the OEMS will advise, in writing, both the CDCA and the principal investigator of the approval as well as any comments from reviewers. The investigator may then contact the CDCA to arrange for the transfer of the requested information, pending approval by the UNC IRB. 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. Exceptions must be approved by the NCTR Research Review Committee and the OEMS Hospital and Trauma Specialist.

If there is a single disapproval, the OEMS 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 OEMS who will distribute the information to the Registry Research Committee who will respond to the OEMS in writing within ten working days. A majority vote of the reviewers is required to over-rule the initial denial for data.

Past experience has demonstrated that the vast majority of requests are approved promptly and uneventfully with this approach, while maintaining the confidentiality of each hospital and guaranteeing that their objections will be heard and acted upon if concerns arise over a data request.

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 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 (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 Publications Committee. An electronic copy of a proposed abstract, manuscript, or presentation, to include the required "Publication Request" form (Attachment C), must be submitted to OEMS (Attention: Sharon Rhyne, Hospital and Trauma Specialist, Sharon.Rhyne@ncmail.net). These applications will be disseminated to the Publications Committee (Attachment E), which consists of four trauma medical directors, one representative from the Trauma System Leaders Committee, one representative from the Registrar Committee, the STAC ISSAC representative, the OEMS Hospital and Trauma Specialist, and the NCTR director. Applicants may be required to present the abstract, manuscript, or presentation to the STAC.

It is possible, and in fact encouraged, that reviewers give constructive criticism without constituting a denial of the application. The Committee will have ten working days (for abstracts) and twenty working days (for manuscripts and presentations) to forward an approval/disapproval by email or in writing (delineating concerns) to the OEMS. 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 Publications Committee who will work with his Committee, with its specific expertise, to

render a final approval or disapproval through the OEMS. A 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 OEMS Hospital and Trauma Specialist an electronic copy of the abstract, manuscript, or presentation with a response to the Publications Committee's concerns. The OEMS shall email the notice of appeal and corresponding materials to the Publications Committee, giving them fifteen working days to forward an approval or disapproval to the OEMS. 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 favorable reply. In the event of a split vote, the Chair shall cast the deciding vote.

RESEARCH REVIEW COMMITTEE APPOINTMENT PROCESS

A Research Review Committee will be appointed by the STAC, in January of every even year, to consist of the trauma medical directors, two representatives from the Trauma System Leaders Committee, two representatives from the Registrar's Committee, a STAC ISSAC representative, the OEMS Hospital and Trauma Specialist, and the NCTR Director. Subsequently, the reviewers will select a chairperson.

PUBLICATIONS COMMITTEE APPOINTMENT PROCESS

A Publications Committee will be appointed by the STAC, in January of every even year, to consist of four trauma medical directors, the North Carolina Committee on Trauma (NCCOT) Research Chair, a representative from the Trauma System Leaders Committee, a representative from the Registrar's Committee, the STAC ISSAC representative, the OEMS Hospital and Trauma Specialist, and the NCTR Director. Subsequently, the reviewers will select a chairperson. The Trauma System Leaders and Registrar's Committee members should be different from those on the Research Review Committee.

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, meaning that 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; and

- 2) Participation in writing the article by contributing to, drafting, or revising it for critically important content; and
- 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 acknowledgment 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 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 its corresponding manuscript.

The OEMS and each individual hospital contributing data to the project shall receive a standard acknowledgment 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."

COMPILATION OF RESEARCH

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

Copies of the Routine Data Requests also shall be forwarded routinely to the OEMS from the CDCA in order to ensure a complete compilation of instances when the registry data base is utilized.

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 Central Data Collection Agency 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 OEMS.
- The OEMS will immediately distribute the application to the Research Review Committee members who shall have **ten** working days to forward an approval/disapproval to the OEMS. 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 OEMS one electronic copy of response to concerns that served as the basis for disapproval of the project.
- The OEMS will immediately distribute the materials to the Research Review Committee which will have **ten** working days to forward an approval/disapproval to the OEMS. Failure to communicate an approval/disapproval by the deadline will be construed as approval of the data request. A majority vote of the reviewers is required to over-rule the original denial for data.

Abstracts, Manuscripts or Presentations:

Initial Requests:

- Complete the required “Publication Request” form and email it with the electronic copy of the proposed abstract, manuscript or presentation to the OEMS.
- The OEMS will immediately distribute the document to the Publications Committee members who will have **ten** working days (for abstracts) and **twenty** working days (for manuscripts and presentations) to forward an approval/disapproval(delineating concerns) to the OEMS. Failure

to communicate an approval or disapproval by the deadline indicates approval of the abstract, manuscript or presentation. Any disapproval shall be simultaneously copied to the Chairman of the Publications Committee who will work with his Committee to render a final decision through the OEMS.

Appeals:

- Applicant forwards to the OEMS one electronic copy of response to the Publications Committee concerns.
- The OEMS will distribute the response to the Publications Committee members, giving them **fifteen** working days to render an approval or disapproval to the OEMS. If the majority of the Publications Committee members approves 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

North Carolina Trauma Registry
Bioinformatics Bldg, Rm 2126
University of North Carolina
Chapel Hill, NC 27599-7050
(919) 966-6263/Fax: (919) 966-6009
e-mail: Sharon_schiro@med.unc.edu

Routine Data Request

INDIVIDUAL REQUESTING INFORMATION:

INSTITUTION: DEPARTMENT:
ADDRESS:
PHONE: FAX: EMAIL:
DATE OF REQUEST: DATE NEEDED:

INFORMATION REQUESTED (Refer to the NCTR Data Dictionary at www.ncems.org/trauma/trauma_registry.html to determine datapoints available for analysis.):

NCTR DATA POINTS and ICD-9 CODES TO BE USED (Refer to the NCTR Data Dictionary at www.ncems.org/trauma/trauma_registry.html to obtain datapoint names.):

PURPOSE OF INQUIRY:

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

NCTR USE ONLY

DATE RECEIVED: DATE COMPLETED:
REQUEST RECEIVED BY::
DATE RDR FORM SENT TO THE OEMS:
DATE ADDED TO TRACKING SYSTEM:

ATTACHMENT B: Scientific Data Request Form

SCIENTIFIC DATA REQUEST
APPLICATION FOR DATA
FROM THE NORTH CAROLINA TRAUMA REGISTRY DATABASE

PROJECT TITLE: _____

PRINCIPAL INVESTIGATOR: _____

TITLE: _____

INSTITUTION: _____

ADDRESS: _____

TELEPHONE: _____

EMAIL ADDRESS: _____

TRAUMA MEDICAL DIRECTOR (PLEASE PRINT): _____

INSTITUTION: _____

WE THE UNDERSIGNED AGREE NOT TO PUBLISH OR PUBLICLY PRESENT DATA PROVIDED FROM THE NORTH CAROLINA TRAUMA REGISTRY WITHOUT PRIOR APPROVAL BY THE PUBLICATIONS COMMITTEE, AND TO GUARD THE CONFIDENTIALITY OF ANY DATA PROVIDED TO US BY THE NORTH CAROLINA TRAUMA REGISTRY.

REQUIRED SIGNATURES:

PRINCIPAL INVESTIGATOR: _____ DATE: _____

TRAUMA MEDICAL DIRECTOR: _____ DATE: _____

PLEASE NOTE: Failure to complete all sections will result in form being returned. Refer to the NCTR Data Dictionary (www.ncems.org/trauma/trauma_registry.htm) to accurately request datapoints 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 NCTR Data Dictionary (www.ncems.org/trauma/trauma_registry.htm) to accurately specify datapoints.

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

North Carolina Trauma Registry
Bioinformatics Bldg, Rm 2126
University of North Carolina
Chapel Hill, NC 27599-7050
(919) 966-6263/Fax: (919) 966-6009
e-mail: Sharon_schiro@med.unc.edu

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:

ATTACHMENT D: NCTR Research Review Committee Membership

Trauma Medical Directors:

Michael Chang
Scott Sagraves
Chip Rich
Mike Thomason
Mike Buechler
Jay Wyatt
Osi Udekwu
Tom Clancy
Richard Ozment
Mike Barringer
Steve Vaslef

Trauma System Leadership Committee representatives:

Diane Wheaton (2003-2005)
Representative to be named (TBN)

Registrar Committee representatives:

Bonnie Snyder (2003-2005)
TBN

STAC ISSAC Representative TBN

Hospital and Trauma Specialist: Sharon Rhyne

NCTR Director: Sharon Schiro

ATTACHMENT E: NCTR Publications Committee Membership

Trauma Medical Directors:

Michael Chang (2003-2005)
Tom Clancy (2003-2005)
Mike Barringer (2003-2005)
Steve Vaslef (2003-2005)
NCCOT Research Chair: Osi Udekwu

Trauma System Leaders Committee representative TBN

Registrar's Committee representative TBN

STAC ISSAC Representative TBN

Hospital and Trauma Specialist: Sharon Rhyne

NCTR Director: Sharon Schiro