

Veterinary Committee on Trauma (VetCOT) Registry Guidelines for Data Use and Authorship

Originally drafted: August 2014

Final approval: January 2015

Last updated: January 2015

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VetCOT Trauma Registry Subcommittee:

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VetCOT Vision and Goals

The Veterinary Committee on Trauma (VetCOT) was formed in 2011 with the intent of creating a network of veterinary trauma centers. The vision was that these centers would work collaboratively to define high standards of care and disseminate information focused on improving trauma patient management, efficiency, and outcome to the veterinary community. The expectation was that these centers would contribute to a trauma registry to allow for the collection of information on veterinary trauma patients and allow for the continued advancement of patient care.

Goals for creating a network of veterinary trauma centers:

- Enhancement of trauma **patient care** (e.g., improved survival, reduction of co-morbidities, development of protocols to improve efficiency and outcomes)
- Enhancement and promotion of **research** collaborations (e.g., development of evidence-based protocols; evaluation of minimally invasive, cost-effective interventions; translational medicine opportunities)
- Expansion and formalization of **education** on veterinary trauma
- Enhancement of the **visibility** of veterinary specialty colleges

Veterinary Trauma Registry History

The VetCOT Registry Subcommittee was formed in 2012 and began compiling information identifying options for establishing a veterinary trauma registry. A document outlining this information was distributed to VetCOT in February 2012 (see “VetCOT Trauma Registry Subcommittee update Feb 2012”). In February 2013, nine Veterinary

Trauma Centers (VTCs) were identified. Thereafter, a proposal was drafted by the committee to establish a veterinary trauma registry using the Research Electronic Data Capture (REDCap) tool. A document outlining the proposal was distributed to VetCOT in May 2013 (see “Proposal for Veterinary Trauma Database Pilot Project May 2013 FINAL”). The trauma database was created in the summer of 2013 and data entry by the nine identified VTCs began in September 2013. As of November 2014, over 3100 canine and feline trauma patients were included in the registry.

Guidelines for Use of Registry Data

The *VetCOT Registry Subcommittee (VetCOT-RS)* members will provide scientific governance and guide overall management of the VetCOT Registry. The VetCOT-RS committee membership will include a majority (+1) of members that are not employed by an identified or verified Veterinary Trauma Center (VTC) and at least 2 members from active VTCs. A major responsibility of the VetCOT-RS is the determination of data elements to be included and the operational definitions of these data elements in the VetCOT Registry. Annually (in January), the data elements included in the registry will be re-evaluated and consideration made to the exclusion of current data elements or inclusion of new data elements. In addition, the VetCOT-RS will approve all applications for use of the VetCOT Registry (database) information to ensure that investigators using the information for research have carefully designed and feasible plans that do not raise ethical or governance concerns.

The *Level I and II VTC leads* will be solicited for their input regarding data elements included in the registry. The opportunity will also be given to VTC leads to request the addition of sub-questionnaires (optional data elements) to the database for the purpose of data collection pertaining to a specific research hypothesis. Additionally, Level I and II VTC leads will be given the opportunity to comment on submitted applications and request to become a co-investigator.

Data Access

Research requests must align with the vision of the VetCOT and be in accordance with ethical principles. All requests for data access must be submitted through a formal application process and must adhere to the specific conditions set forth on the application. Applications for data will be accepted from any ACVECC Diplomate or ACVECC resident-in-training under the advisement of an ACVECC Diplomate.

VTCs have the ability to utilize their center’s data at any time. Although formal request for data is not required, notification to the VetCOT-RS of intent to publish single center data, including research question, is encouraged (in an effort to avoid duplication with proposed multi-center projects). Appropriate acknowledgements of the VetCOT and REDCap are required (see below).

Application Process

The VetCOT-RS will review applications/requests for database information annually. Applications will be solicited in January and approval or feedback will be provided to applicants within 60 days after submission. Initially, up to 3 applications will be approved per year.

- a) Each request must be accompanied by a research proposal (application template provided) and approval of the mentor if the requester is a resident.
- b) Data analyses must be conducted using protocols that ensure privacy and security of the data and will not identify individual owners, cases, or institutions.
- c) VetCOT-RS members will be given 3 weeks to review the submitted application, score the application using a grading scheme, and provide comments to the VetCOT-RS lead, as well as a decision to “accept” or “not accept” the submitted application. Applications accepted by a majority of VetCOT-RS members will be considered “accepted”. In the event of a tie, the VetCOT-RS lead will decide whether or not the application should be accepted. VetCOT-RS members who have submitted an application will not be permitted to participate in the scoring of their application.
- d) Accepted applications will then be forwarded to the Level I and II VTC leads who will be given 3 weeks to provide comments to the VetCOT-RS lead and indicate if they would like to be included as a co-investigator.
- e) All application scores, comments, and requests for co-investigation will then be compiled by the VetCOT-RS lead and notification of approval or provision of feedback will be given to all applicants within 2 weeks.

Reporting/Publishing

The VetCOT-RS will require a biannual (every 6 months) progress report including updates on the submission of the proposed manuscript after provision of the requested database information. Manuscript submissions should occur within **12 months** of obtaining the requested database information. However, if additional retrospective data collection is planned as part of the research proposal, manuscript submissions should occur within **18 months** of obtaining the requested database information. Should unforeseeable circumstances arise, researchers can apply for an extension to the VetCOT-RS lead. After that time, database information will be relinquished from that researcher and applications from other researchers to investigate that research hypothesis will be considered.

Information regarding specific cases from each VTC must remain confidential. Failure to omit personal identifying data of VTC cases/owners/institutions outside of the approved data elements may prevent subsequent approval of applications for Registry data use.

Authorship of Publication

Automatic authorship of manuscripts will not be granted to VetCOT members or VTC leads unless significant contributions to the manuscript are made in accordance with the targeted journal's author guidelines. However, "Veterinary Committee on Trauma" should be included as the last author on all publications, if permitted by the targeted journal. *J Vet Emerg Crit Care* has approved this method of authorship; however, *J Vet Intern Med* has not (email communications, September 2014).

Acknowledgements in Publications

The following statement must be included in the acknowledgments section of all publications: "The research on which this presentation is based used data from the Veterinary Committee on Trauma Registry and we are grateful to the Veterinary Trauma Centers that participated. The Veterinary Committee on Trauma assumes no responsibility for the interpretation of the Registry data."

Acknowledgement of the VetCOT-RS members and a list of the Level I and II VTC Leads and those involved in data entry at each Center for the time period of Registry data used must also be included. This information will be collected annually by the VetCOT-RS lead and provided to the researchers.

The following acknowledgement must also be included: "The project described was supported by Award Number UL1TR000114 from the National Center for Advancing Translational Sciences of the National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Center For Research Resources or the NIH. Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Minnesota".¹

¹Paul A. Harris, Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, Jose G. Conde, Research electronic data capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support, *J Biomed Inform.* 2009 Apr;42(2):377-81.

Open (free online) access to publications that result from VetCOT Registry data use is not required. However, once abstracts or manuscripts are published online, **electronic journal links should be provided to the REDCap administration** (redcap@vanderbilt.edu).

Data analysis expertise/statistical consultation must be provided by the applicant/requester and is not the responsibility of the VetCOT-RS.

Responsibilities of the VetCOT-RS include:

1. Oversee database management including:
 - a. database content development (selection and operational definitions of data elements) and maintenance
 - b. data ownership, access regulation, and privacy
 - c. auditing and data integrity checks
 - d. linkage with other established registries
 - e. data security and back-up (provided by REDCap)
2. Database infrastructure development and maintenance
3. Review and approve requests for data access
4. Review and approve data collaboration initiatives with other groups

Responsibility of the Data Coordinator (person that handles the data elements and has access to the database):

1. Compile and export the requested data from the VetCOT Registry to a format deemed suitable by the requester (e.g., excel, SAS).

Responsibility of the Level I and II VTC Leads:

1. Ensure timely data entry in the VetCOT Registry. Ideally, information is collected prospectively and verification of information using medication records can occur retrospectively within 30 days of the animal's discharge from the hospital or death. However, all REDCap information must be up-to-date on a quarterly basis (March 31st, June 30th, September 30th, December 31st) *such that all cases admitted up to that date will be entered in the database within 30 days.*
2. Promptly notify the VetCOT-RS if data entry is not possible or if errors in data entry occur.
3. Provide the names of persons responsible for data entry at their Center annually so that appropriate recognition can be given.