TRAUMA REGISTRY DATA REQUEST POLICY

INTRODUCTION

COTS is a group of physicians, healthcare professionals, and other experts working together to improve the health and safety of our communities.

The COTS Trauma Registry is a repository for data dating back to January 1999. Early years of the COTS Trauma Registry are representative of a more minimal dataset than current years. COTS Trauma Registry data is inclusive of trauma patients who are admitted into or die at a hospital as well as patients who are transferred from one hospital to another for further evaluation after an injury. For a complete description of COTS Trauma Registry inclusion criteria, see the COTS Trauma Registry Data Elements (***Exhibit A***). The COTS Trauma Registry captures demographic, clinical, and outcome data from participating Central, Southeast, and Southeast Central Ohio hospitals. The intent of Central, Southeast, and Southeast Central Ohio hospitals and COTS in sharing such data is to improve trauma care, research, and injury prevention efforts. COTS member institutions that directly contribute data to the COTS Trauma Registry are listed in ***Exhibit B***

REQUEST & APPROVAL PROCESS FOR DATA FROM COTS TRAUMA REGISTRY

COTS Trauma Registry has three options for requesting data:

1. Expedited
2. Comprehensive
3. Special Approval

Except for the Special Approval Process for Data Owners option, no data is ever released that would directly identify a single patient or institution.

For data requests, the requester should review the COTS Trauma Registry Data Elements (***Exhibit A***). Specific data elements identifying patients, health care agencies, providers, or emergency medical service (EMS) agencies that are not available to be released are indicated under “Elements Never Released”.

Data request applications should be submitted to the COTS Regional Data Systems Coordinator, 1390 Dublin Road, Columbus, Ohio 43215. For more information, inquires can be made to the COTS Regional Data Systems Coordinator at https://www.cotshealth.org/about-us/staff

Expedited Data Approval Process: This expedited review process allows COTS to release de-identified data in an aggregate report. Aggregate, de-identified data provides summarized information to answer a specific question. Use of COTS aggregate, de-identified data does not require a Data Use Agreement. Aggregate data that may identify a group of COTS member institutions (i.e. trauma centers vs. acute care hospitals) or a county with only one hospital will need to be reviewed and approved by the COTS Research Council chair before release. If it is a conflict of interest to have the Research Council Chair approve the data request, the president of the Trauma Advisory Board will approve the release, provided there is no conflict of interest, If there is a conflict of interest with both the chair and president, the data request will be presented at the TAB (Trauma Advisory Board) for a group decision,

Necessary document to submit for final approval:

- Expedited Data Request Form (***Exhibit C***)

If the data request is approved, the data will be released to the requester. Aggregate or accumulative data without patient or institution identifiers will be sent via email to the requester.

If the requested data is not approved for release, the data requester will receive notification that their request was denied from the COTS President by e-mail. The President will indicate the reason for the denial. The requester will have the option of clarifying, restructuring, or re-submitting requests for another attempt for approval.

Comprehensive Data Approval Process: This comprehensive review process allows COTS to release de-identified data and/or a Limited Data Set (LDS) as defined under the HIPAA regulations for research or QI inquiries. No requester shall have access to the entire set of data elements; only those data elements specifically requested will be released.

Necessary documents to submit for final approval:

- Comprehensive Data Request Form (***Exhibit D***)
- Internal/Investigational Review Board (IRB) Approval or Exemption Documents, if applicable
- IRB Study Protocol, if applicable
- Data Use Agreement (***Exhibit E***) or Data Use Agreement for Governmental Agencies (***Exhibit F***)

The Comprehensive Data Approval Process warrants review and approval via the COTS Research Council chair or the president of the Trauma Advisory Board (TAB) if there is a conflict of interest with the Research Council chair. If both the chair and President, have a conflict of interest, the research will be presented at TAB for a group review and approval. The COTS Research Council chair, TAB president, or TAB reserves the right to request assurance of outside IRB approval or exemption. The COTS Research Council chair, Trauma Advisory Board president, or TAB shall have the right to consult a representative from the COTS Registry Subcommittee and/or COTS Legal Counsel to assist in the approval process. If Legal Counsel is required to participate in the approval process, the requester will be assessed all associated legal fees.

If the data request is approved, the data will be released to the requester. Approved data releases that include non-aggregate information will be released according to COTS HIPAA policy.

If the requested data is not approved for release, the data requester will receive notification that the request was denied from the COTS President by e-mail. The President will indicate the reason for the denial. The requester will have the option of clarifying, restructuring, or re-submitting requests for another attempt for approval.

Special Approval Process for Data Owners: Each institution that submits data to the COTS Trauma Registry owns their individual institutional data housed at COTS. A Trauma Medical Director, Trauma Program Manager/Director, and/or Trauma Data Registrar from our member institutions (***Exhibit B***) may request a report of their own institutional data for review or audit purposes. The Emergency Department (ED) Manager/Director and/or data input personnel from acute care hospitals (***Exhibit B***) and free-standing emergency departments (FSED) may request a report of their own institutional data for review or audit purposes.

Necessary document to submit for final approval:

- Expedited Data Request Form (***Exhibit C***)

DATA SOURCE ACKNOWLEDGEMENT

Data requesters must agree to cite the COTS Registry as the source of the data to project-related planning sessions or performance improvement committees. Any publications related to this project must give credit to the COTS Registry for use of data. Copies of any public or professional articles utilizing COTS data should be forwarded to COTS upon publication. Data requesters may not publicize information that includes non-aggregate data or identifiers constituting a Limited Data Set. The Data Use Agreement must be strictly followed regarding information received in response to a request under the Comprehensive Review Approval Process.

USE OF COTS DATA FOR HUMAN SUBJECTS RESEARCH

The Office of Human Research Protections (OHRP) under the U.S. Department of Health & Human Services (HHS) regulates "human subjects' research." However, research involving only information about individuals, and that does not involve intervention or interaction with the individuals, is not covered by the regulations if the research does not involve individually identifiable information. The COTS Trauma Registry does not provide individually identifiable information and therefore the research is not covered by the "human subjects' research" regulations.

CELL SUPPRESSION POLICY

For data released under the ***Expedited Data Approval Process*** or ***Comprehensive Data Approval Process***, any recipient must follow the following requirements related to cell value:

- No cell (e.g. admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. A value of *zero* does not violate the minimum cell size policy.
- No cell can be reported that allows a value of 1 to 10 to be derived from other reported cells or information. For example, the use of percentages or other mathematical formulas that, in combination with other reported information, result in the display of a cell containing a value of 1 to 10 are prohibited.
- The cell suppression policy also applies to the reporting of excluded cases.

COTS Board approval January 2002. Updated April 2003, October 2003, March 2004, November 2006, May 2009, August 2009, April 2016, May 2016, May 2017, Feb 2018, May 2021, May 2022, November 2022, January 2023

EXHIBIT A: ALL COTS TRAUMA REGISTRY DATA ELEMENTS

Elements Never Released

Trauma Number
Institute Number
Unique Patient Admission Number
EMS Provider Name
EMS Patient Care Report Unique Identifier (UUID)
Transferring Hospital Code
Transfer to Hospital

Elements Released only as a Limited Data Set

Patient's Home City
Patient's Home County
Patient's Home Zip Code
Alternative Home Residence
Date of Birth
Incident City^
Incident County^
Incident Location Zip Code^
Pre-Hospital Dispatch Date to Scene or Transferring Facility
Pre-Hospital Date Arrived at Scene or Transferring Facility
Pre-Hospital Date Left Scene or Transferring Facility
ED/Hospital Arrival Date
Trauma Surgeon Arrival Date◆
ED Discharge Order Written Date*
ED Discharge Date
Procedure Start Date
Hospital Discharge Order Written Date*
Hospital Discharge Date
Injury Incident Date

Elements Released as De-Identified Data

Facility Type★
Patients Home State
Patient's Home Country
Sex
Age (89 and under only; ages over 89 will be listed together as "90 or older")
Age Units
Race
Ethnicity
ICD-9 Primary E Code√
ICD-10 Primary E Code+
ICD-9 Additional E Code√
ICD-10 Additional E-Code+
ICD-9 Location E-Code√
ICD-10 Location E-Code+
Work Related Injury
Patients Occupational Industry^
Patients Occupation^
Injury Incident Time^
Incident State
Incident Country^
Protective Devices
Child Specific Restraint
Airbag Deployment
Transport Mode for Arrival at Your Facility
Other Transport Modes^
Scene EMS Run Sheet Present
Pre-Hospital Dispatch Time to Scene or Transferring Facility
Pre-Hospital Time Arrived at Scene or Transferring Facility
Pre-Hospital Time Left Scene or Transferring Facility
Scene Extrication√
Scene Delay◆◆
Initial Field Systolic Blood Pressure
Initial Field Pulse Rate
Initial Field Respiratory Rate
Initial Field Oxygen Saturation^
Initial Field GCS Eye Opening
Initial Field GCS Verbal Opening
Initial Field GCS Motor Opening
Initial Field GCS Total Score
Initial Field GCS Qualifier
Scene Intervention
Pre-Hospital Cardiac Arrest+
Inter-Facility Transfer
Emergency Department (ED)/Hospital Arrival Time
Trauma Type
Trauma Activation Level
Trauma Surgeon Arrival Time◆
Initial ED/Hospital Systolic Blood Pressure
Initial ED/Hospital Pulse Rate
Initial ED/ Hospital Respiratory Rate
Initial ED/Hospital Respiratory Assistance^
Initial ED/Hospital Oxygen Saturation^
Initial ED/Hospital Supplemental Oxygen^
Initial ED/Hospital Temperature
Initial ED/Hospital GCS Eye Opening
Initial ED/Hospital GCS Verbal Response
Initial ED/Hospital GCS Motor Response
Initial ED/Hospital GCS Assessment Qualifier
Height^
Weight^
ED Discharge Order Written Time*
ED Discharge Time
ED Discharge Disposition
Alcohol Screen
Alcohol Screen Results
Drug Screen Results
Admitting Specialty
ICD-9 Hospital Procedure Codes√
ICD-10 Hospital Procedure Codes*
Procedure Episode
Procedure Start Time
Procedure Location
Pre-Existing Conditions (Comorbids)
DNR Status^
ICD-9 Diagnosis
ICD-10 Diagnosis+
Abbreviated Injury Scale (AIS) Body Region
AIS Pre-Dot Code
AIS Severity
Injury Severity Score(ISS)
Hospital Length of Stay in Days
Total ICU Length of Stay
Total Vent Days
Hospital Discharge Order Written Time*
Hospital Discharge Time
Hospital Discharge Disposition
Outcome
Primary Method of Payment
Hospital Complications

^ No data prior to 2013
+ No data prior to 2015
√ No data after to 2015
***No data prior to 2016**
◆ No data prior to 2021
√√No data after 2022
◆ ◆ No data prior to 2022

★ Level I adult I, II, & ped Level I will be combined due to # of facilities in registry

EXHIBIT B: COTS MEMBER INSTITUTIONS

The following are COTS member-institutions as of May 2022. A COTS member-institution is one who directly contributes trauma patient data to the COTS Trauma Registry.

COTS Trauma Center Hospitals:

Genesis Hospital, Zanesville, Ohio, Level III Trauma Center
Marietta Memorial Hospital, Marietta, Ohio, Level III Trauma Center
Mount Carmel East, Columbus, Ohio, Level II Trauma Center
Nationwide Children's Hospital, Columbus, Ohio, Level I Trauma Center
The Ohio State University Hospital East, Columbus, Ohio, Level III Provisional Trauma Center
The Ohio State University Wexner Medical Center, Columbus, Ohio, Level I Trauma Center
OhioHealth Grant Medical Center, Columbus, Ohio, Level I Trauma Center
OhioHealth Riverside Methodist Hospital, Columbus, Ohio, Level II Trauma Center

COTS Acute Care Hospitals and Free-Standing Emergency Departments:

Adena Fayette Medical Center, Washington Court House, Ohio
Adena Greenfield Medical Center, Greenfield, Ohio
Adena Pike Medical Center, Waverly, Ohio
Adena Regional Medical Center, Chillicothe, Ohio
Coshocton Regional Medical Center, Coshocton, Ohio
Diley Ridge Medical Center, Canal Winchester, Ohio
East Ohio Regional Hospital, Martins Ferry, Ohio
Fairfield Medical Center, Lancaster, Ohio
Fairfield Medical Center River Valley Campus, Lancaster, Ohio
Holzer Gallipolis, Gallipolis, Ohio
Holzer Medical Center – Jackson, Jackson, Ohio
Holzer Meigs Emergency Department, Pomeroy, Ohio
King's Daughters Medical Center, Portsmouth, Ohio
Knox Community Hospital, Mt. Vernon, Ohio
Licking Memorial Hospital, Newark, Ohio
Madison Health, London, Ohio
Marietta Belpre Medical Campus, Belpre, Ohio
Marietta Selby General Hospital Campus, Marietta, Ohio
Mary Rutan Hospital, Bellefontaine, Ohio
Memorial Health, Marysville, Ohio
Morrow County Hospital, Mt. Gilead, Ohio
Mount Carmel Franklinton, Columbus, Ohio
Mount Carmel Grove City, Grove City, Ohio
Mount Carmel Lewis Center, Lewis Center, Ohio
Mount Carmel New Albany, New Albany, Ohio
Mount Carmel Reynoldsburg, Reynoldsburg, Ohio
Mount Carmel St. Ann's, Westerville, Ohio
Nationwide Children's Lewis Center, Delaware, Ohio
OhioHealth Berger, Circleville, Ohio
OhioHealth Doctors Hospital, Columbus, Ohio
OhioHealth Dublin Methodist Hospital, Dublin, Ohio
OhioHealth Grady Memorial Hospital, Delaware, Ohio

OhioHealth Grove City Methodist Hospital, Grove City, Ohio
OhioHealth Hardin Memorial Hospital, Hardin, Ohio
OhioHealth Hilliard, Hilliard, Ohio
OhioHealth Lewis Center, Delaware, Ohio
OhioHealth Marion General Hospital, Marion, Ohio
OhioHealth New Albany, New Albany, Ohio
OhioHealth O'Bleness Hospital, Athens, Ohio
OhioHealth Obetz, Columbus, Ohio
OhioHealth Pickerington Emergency Care Center, Pickerington, Ohio
OhioHealth Powell, Columbus, Ohio
OhioHealth Reynoldsburg, Reynoldsburg, Ohio
OhioHealth Westerville Emergency Care Center, Westerville, Ohio
Southeastern Ohio Regional Medical Center, Cambridge, Ohio
Southern Ohio Medical Center, Portsmouth, Ohio
Trinity Medical Center West, Steubenville, Ohio
Wyandot Memorial Hospital, Upper Sandusky, Ohio

This page may be updated upon membership changes independent of general policy updates.

COTS
An affiliate of the Columbus Medical Association

EXHIBIT C: EXPEDITED DATA REQUEST FORM

Requester Name & Credentials:	
Title:	
Institution:	
Phone No:	**Email:**

What question is the data requester wanting to answer with COTS data?

Dates of Inclusion of Data (from Month/Year through Month/Year)

If data is to be stratified by subgroup, what subgroup? Example stratify sex by age.
(Further clarification will be made with COTS)

***REMINDER –** Reported data must follow the Cell Suppression Policy. No cell containing a value of 1 to 10 can be reported directly. A value of *zero* does not violate the minimum cell size policy. No cell can be reported that allows a value of 1 to 10 to be derived from other reported cells or information.

Please indicate how the data will be used. Check all that apply.

☐ Own Department/Unit Use ☐ Own Hospital/Agency Use
☐ Department/Unit/Hosp/Agency use other than own: _____
☐ Educational Purposes ☐ Research
☐ Publication ☐ Public Policy
☐ Public Health ☐ Other: _____

Please indicate how the data will be stored. Check all that apply.

☐ Double-lock file storage cabinet ☐ Password-protected desk-top computer
☐ Laptop with password protection & anti-theft encryption software
☐ Other: _____

Continued on next page

Please acknowledge the following: ☐ *COTS will be acknowledged as a source of information in materials being presented and/or published.* ☐ *COTS will receive a project summary at the completion of the project.*	
Signature of Data Requester:	**Date:**
COTS Expedited Data Request Form should be submitted to COTS, 1390 Dublin Road Columbus, Ohio 43215 or rgiambri@cotshealth.org	
For COTS Use Only:	
The following data will be released:	
Approval for Release of Data:	**Date:**
Data Released By:	**Date:**

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EXHIBIT D: COMPREHENSIVE DATA REQUEST FORM

Title of Study or Project:	
Sponsor/Advisor if Applicable:	
Requester Name & Credentials:	**Title:**
Institution:	
Institution Address:	
Phone No:	**Email:**

What question is the data requester wanting to answer with COTS data?

Dates of Inclusion of Data (from Month/Year through Month/Year):

Parameters for Data (i.e. ICD-10 diagnosis codes, mechanism of injuries, zip codes/counties)

***REMINDER –** Reported data must follow the Cell Suppression Policy. No cell containing a value of 1 to 10 can be reported directly. A value of *zero* does not violate the minimum cell size policy. No cell can be reported that allows a value of 1 to 10 to be derived from other reported cells or information.

What is the target audience for the study/investigation?

Indicate how results will be disseminated to the target audience:

Is this project funded?
☐ No ☐ Yes, by:_____ In the amount of $_____

Please indicate how the data will be used. Check all that apply.
☐ Own Department/Unit Use ☐ Own Hospital/Agency Use
☐ Department/Unit/Hosp/Agency use other than own: _____
☐ Educational Purposes ☐ Research
☐ Publication ☐ Public Policy
☐ Public Health ☐ Other: _____

Continued on next page

Please indicate how the data will be stored. Check all that apply.

☐ Double-lock file storage cabinet ☐ Password-protected desk-top computer
☐ Laptop with password protection & anti-theft encryption software ☐ Other:_____

(Copy of IRB Approval/ Exemption and Study Protocol MUST be submitted with this form)

If the request is for individual data elements, please check the specific data elements being requested.

- ☐ Facility Type
- ☐ Patient's Home State
- ☐ Patient's Home Country
- ☐ Sex
- ☐ Age (≥ 90 grouped together)
- ☐ Age Units
- ☐ Race
- ☐ Ethnicity
- ☐ ICD-9 Primary E Code
- ☐ ICD-10 Primary E Code
- ☐ ICD-9 Additional E Code
- ☐ ICD-10 Additional E Code
- ☐ ICD-9 Activity E Code
- ☐ ICD-10 Activity E Code
- ☐ ICD-9 Location Code
- ☐ ICD-10 Location Code
- ☐ Work Related Injury
- ☐ Patients Occupational Industry
- ☐ Patients Occupation
- ☐ Injury Incident Time
- ☐ Incident State
- ☐ Protective Devices
- ☐ Child Specific Restraint
- ☐ Airbag Deployment
- ☐ Transport Mode for Arrival to Facility
- ☐ Other Transport Modes
- ☐ Scene EMS Run Sheet Present
- ☐ EMS Dispatch Time to Scene/Transfer Hospital
- ☐ EMS Arrival Time to Scene/Transfer Hospital
- ☐ EMS Left Time to Scene/Transfer Hospital
- ☐ Scene Extrication
- ☐ Scene Delay
- ☐ Initial Field Systolic Blood Pressure
- ☐ Initial Field Pulse Rate
- ☐ Initial Field Resp Rate
- ☐ Initial Field Oxygen Saturation
- ☐ Initial Field GCS Eye Opening
- ☐ Initial Field GCS Verbal Response
- ☐ Initial Field GCS Motor Response
- ☐ Initial Field GCS Total Score
- ☐ Initial Field GCS Qualifier
- ☐ Scene Intervention
- ☐ Pre-Hospital Cardiac Arrest
- ☐ Inter-Facility Transfer
- ☐ ED/Hospital Arrival Time
- ☐ Trauma Type
- ☐ Trauma Activation Level
- ☐ Trauma Surgeon Arrival Time
- ☐ Initial ED/Hosp Sys Blood Pressure
- ☐ Initial ED/Hosp Pulse Rate
- ☐ Initial ED/Hosp Respiratory Rate
- ☐ Initial ED/Hosp Resp Assistance
- ☐ Initial ED/Hosp Oxygen Saturation
- ☐ Initial ED/Hosp Supplemental Oxygen
- ☐ Initial ED/Hosp Temperature
- ☐ Initial ED/Hosp GCS Eye Opening
- ☐ Initial ED/Hosp GCS Verbal Response
- ☐ Initial ED/Hosp GCS Motor Response
- ☐ Initial ED/Hosp GCS Qualifier
- ☐ Height
- ☐ Weight
- ☐ ED Discharge Order Written Time
- ☐ ED Discharge Time
- ☐ ED Discharge Disposition
- ☐ Alcohol Screen
- ☐ Alcohol Screen Results
- ☐ Drug Screen Results
- ☐ Admitting Specialty
- ☐ ICD-9 Hospital Procedures
- ☐ ICD-10 Hospital Procedures
- ☐ Procedure Episode
- ☐ Procedure Start Time
- ☐ Pre-existing Conditions
- ☐ DNR Status
- ☐ ICD-9 Diagnosis
- ☐ ICD-10 Diagnosis
- ☐ AIS Body Region
- ☐ AIS Pre-Dot Code
- ☐ AIS Severity
- ☐ Injury Severity Score (ISS)
- ☐ Hospital Length of Stay
- ☐ ICU Length of Stay
- ☐ Vent Days
- ☐ Hospital Discharge Order Written Time
- ☐ Hospital Discharge Time
- ☐ Hospital Discharge Disposition
- ☐ Outcome
- ☐ Primary Method of Payment
- ☐ Hospital Complications

Individual Data Elements Released in a Limited Data Set:

- ☐ Patient's Home City
- ☐ Patient's Home County
- ☐ Patient's Home Zip Code
- ☐ Alternative Home Residence
- ☐ Date of Birth
- ☐ Injury Incident Date
- ☐ Incident City
- ☐ Incident County
- ☐ Incident Location Zip Code
- ☐ EMS Dispatch Date to Scene/Transfer Hospital
- ☐ EMS Arrival Date to Scene/Transfer Hospital
- ☐ EMS Left Date to Scene/Transfer Hospital
- ☐ ED/Hospital Arrival Date
- ☐ Trauma Surgeon Arrival Date
- ☐ ED Discharge Order Written Date
- ☐ ED Discharge Date
- ☐ Procedure Start Date
- ☐ Hospital Discharge Order Written Date
- ☐ Hospital Discharge Date

Continued on next page

Additional information not provided above:	
Please acknowledge the following ☐ *COTS will be acknowledged as a source of information in materials being presented and/or published.* ☐ *COTS will receive a project summary at the completion of the project.*	
Signature of Data Requester:	**Date:**
COTS Expedited Data Request Form should be submitted to COTS, 1390 Dublin Road Columbus, Ohio 43215 or rgiambri@cotshealth.org	
For COTS Use Only:	
The following data will be released: **Copy of IRB approval/exemption received on: _____** **Study Protocol received on: _____**	
Approval for Release of Data:	***Date:***
Data Released By:	***Date:***

EXHIBIT E: DATA USE AGREEMENT

This Data Use Agreement (the "Agreement") is effective as of _____ __, 20__ (the "Effective Date") by and between COTS and _____ ("Data User").

RECITALS

WHEREAS, COTS has entered into certain Provider Agreements (the "Provider Agreements") that authorize COTS to disclose certain trauma data and information from its regional trauma registry (the "Trauma Data");

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, pursuant to the request attached hereto as Exhibit A (the "Request"), Data User has requested certain Trauma Data for use by Data User in performance of the Activities (the "Requested Trauma Data");

WHEREAS, COTS has approved the Request and desires to disclose the Requested Trauma Data in the form of a Limited Data Set (as hereinafter defined); and

WHEREAS, COTS wishes to ensure that Data User will appropriately safeguard such Limited Data Set in accordance with the terms and conditions of this Agreement, the Provider Agreements, HIPAA and the HIPAA Regulations.

NOW THEREFORE, COTS and Data User agree as follows:

1. **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as defined in HIPAA and the HIPAA Regulations.

a. "*HIPAA*" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

b. "*HIPAA Regulations*" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.

c. "*Individually Identifiable Health Information*" means information that is a subset of health information, including demographic information collected from an individual, and;

(1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) relates to the past, present, or future physical or mental health or condition

of an individual; or the past, present or future payment for the provision of health care to an individual; and

a) that identifies the individual; or

b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

d. "*Protected Health Information*" or "*PHI*" means Individually Identifiable Health Information that is transmitted by electronic media; maintained in any medium described in the definition of other term *electronic media* in the HIPAA Regulations; or transmitted or maintained in any other form or medium.

2. **Obligations of COTS.**

a. *Limited Data Set*. COTS shall disclose the Requested Trauma Data to Data User in the form of a Limited Data Set. The Limited Data Set shall include the data elements and/or the Limited Data Set Module that have been approved for release in accordance with the COTS Data Request Policy, as amended from time to time. Data User acknowledges and agrees that such Limited Data Set shall not contain any of the following identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual: names, postal address information, other than town or city, State, and zip code; telephone numbers, fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voiced prints; and full face photographic images and any comparable images.

3. **Obligations of Data User.**

a. *Performance of Activities*. Data User may use and disclose the Limited Data Set received from COTS only in connection with the purposes indicated in the Request. Data User shall limit the use or receipt of the Limited Data Set to members of the research team associated with the project designated in the Request.

b. *Nondisclosure Except As Provided In Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

c. *Use or Disclosure As If Cover Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if Data User were a Covered Entity.

d. *Identification Of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.

e. *Disclosures Required by Law*. Data user shall not, without the prior written consent of the COTS, disclose the Limited Data Set on the basis that such disclosure is required by law without notifying COTS so that the COTS shall have the opportunity to fulfill its obligations under the Provider Agreements.

f. *Safeguards*. Data User shall use any and all appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.

g. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent or subcontractor of Data User except with the prior written consent of COTS. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agrees in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.

h. *Reporting*. Data User shall report to COTS within three (3) days of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.

i. *Cell Suppression Policy.* Data User must follow the following requirements related to cell value:

- No cell (e.g. admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. A value of *zero* does not violate the minimum cell size policy.
- No cell can be reported that allows a value of 1 to 10 to be derived from other reported cells or information. For example, the use of percentages or other mathematical formulas that, in combination with other reported information, result in the display of a cell containing a value of 1 to 10 are prohibited.
- The cell suppression policy also applies to the reporting of excluded cases.

4. **Materials Breach, Enforcement and Termination.**

a. *Term*. This Agreement shall be effective as of the Effective Date, and shall continue until the Agreement is terminated in accordance with the provisions of Section 4(c).

b. *COTS's Rights of Access and Inspection*. From time to time upon reasonable notice, or upon a reasonable determination by COTS that Data User has breached this Agreement, COTS may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. The fact that COTS inspects, or fails to inspect, or has the right to inspect, Data User's facilities, systems and procedures does not relieve Data User or its responsibility to comply with this Agreement, nor does COTS's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of COTS's enforcement or termination rights and obligations under this Section 4(b). This Section 4(b) shall survive termination of the Agreement.

c. *Termination*. This Agreement is effective as of the Effective Date and may be terminated by either party, with or without cause, upon ten (10) days written notice to the other party.

d. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

e. *Reporting*. Data User acknowledges and agrees that if COTS's efforts to cure any breach or end any violation are unsuccessful, and if termination of this Agreement is not feasible, COTS shall report to Provider such non-compliance by Data User of which COTS becomes aware, and Data User agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against COTS with respect to such report(s).

f. *Disposition of Records*. Upon termination of this Agreement, if PHI provided pursuant to this Agreement is retained in such a form by Data User to make the return of such PHI infeasible, Data User shall extend the protections of this Agreement to such PHI. Data user shall return or destroy all other PHI that was provided to Data User pursuant to this Agreement. This section shall survive termination of this Agreement.

g. *Injunctions*. COTS and Data User agree that any violations of the provisions of this Agreement may cause irreparable harm to COTS. Accordingly, in addition to any other remedies available to COTS at law, in equity, or under this Agreement, in the event of any violation by Data User of any of the provisions of this Agreement, or any explicit threat thereof, COTS shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof, without bond or other security being required and without the necessity of demonstrating actual damages. The parties' respective rights and obligations under this Section 4(g) shall survive termination of the Agreement.

h. *Indemnification.* Data User shall indemnify, hold harmless and defend COTS from and against any and all claims, losses, liabilities, costs and other expenses resulting from, or relating to, the acts or omissions of Data User in connection with the representations, duties and obligations of Data User under this Agreement. The parties' respective rights and obligations under this Section 4(h) shall survive termination of the Agreement.

5. **Miscellaneous Terms.**

a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from an individual who is a subject of the PHI from which the Limited Data Set was created, or written authorization from any other person, where such authorization would be required under state law for such use or disclosure.

b. *Amendment*. COTS and Data User agree that amendment of this Agreement may be required to ensure that COTS and Data User comply with corresponding amendments to the Provider Agreements regarding changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set.

c. *No Third Party Beneficiaries*. Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person or than COTS and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.

d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with the Provider Agreements, and/or applicable law protecting the privacy, security, and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Effective Date.

COTS	DATA USER:
_____	_____
Signature	*Signature*
_____	_____
Printed Name, Title	*Printed Name, Title*
_____	_____
Date	*Date*

EXHIBIT F: DATA USE AGREEMENT GOVERNMENT EMPLOYEES

This Data Use Agreement (the "Agreement") is effective as of _____ __, 20__ (the "Effective Date") by and between COTS and _____ ("Data User").

RECITALS

WHEREAS, COTS has entered into certain Provider Agreements (the "Provider Agreements") that authorize COTS to disclose certain trauma data and information from its regional trauma registry (the "Trauma Data");

WHEREAS, Data User performs certain Activities (as hereinafter defined);

WHEREAS, pursuant to the request attached hereto as Exhibit A (the "Request"), Data User has requested certain Trauma Data for use by Data User in performance of the Activities (the "Requested Trauma Data");

WHEREAS, COTS has approved the Request and desires to disclose the Requested Trauma Data in the form of a Limited Data Set (as hereinafter defined); and

WHEREAS, COTS wishes to ensure that Data User will appropriately safeguard such Limited Data Set in accordance with the terms and conditions of this Agreement, the Provider Agreements, HIPAA and the HIPAA Regulations.

NOW THEREFORE, COTS and Data User agree as follows:

1. **Definitions.** The parties agree that the following terms, when used in this Agreement, shall have the following meanings, provided that the terms set forth below shall be deemed to be modified to reflect any changes made to such terms from time to time as defined in HIPAA and the HIPAA Regulations.

a. "*HIPAA*" means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.

b. "*HIPAA Regulations*" means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164.

c. "*Individually Identifiable Health Information*" means information that is a subset of health information, including demographic information collected from an individual, and;

(1) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) relates to the past, present, or future physical or mental health or

condition of an individual; or the past, present or future payment for the provision of health care to an individual; and

a) that identifies the individual; or

b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

d. "*Protected Health Information*" or "*PHI*" means Individually Identifiable Health Information that is transmitted by electronic media; maintained in any medium described in the definition of other term *electronic media* in the HIPAA Regulations; or transmitted or maintained in any other form or medium.

2. **Obligations of COTS.**

a. *Limited Data Set*. COTS shall disclose the Requested Trauma Data to Data User in the form of a Limited Data Set. The Limited Data Set shall include the data elements and/or the Limited Data Set Module that have been approved for release in accordance with the COTS Data Request Policy, as amended from time to time. Data User acknowledges and agrees that such Limited Data Set shall not contain any of the following identifiers of the individual who is the subject of the Protected Health Information, or of relatives, employers or household members of the individual: names, postal address information, other than town or city, State, and zip code; telephone numbers, fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voiced prints; and full face photographic images and any comparable images.

3. **Obligations of Data User.**

a. *Performance of Activities*. Data User may use and disclose the Limited Data Set received from COTS only in connection with the purposes indicated in the Request. Data User shall limit the use or receipt of the Limited Data Set to members of the research team associated with the project designated in the Request.

b. *Nondisclosure Except As Provided In Agreement*. Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement.

c. *Use or Disclosure As If Cover Entity*. Data User may not use or disclose the Limited Data Set in any manner that would violate the requirements of HIPAA or the HIPAA Regulations if Data User were a Covered Entity.

d. *Identification Of Individual*. Data User may not use the Limited Data Set to identify or contact any individual who is the subject of the PHI from which the Limited Data Set was created.

e. *Disclosures Required by Law*. Data user shall not, without the prior written consent of the COTS, disclose the Limited Data Set on the basis that such disclosure is required by law without notifying COTS so that the COTS shall have the opportunity to fulfill its obligations under the Provider Agreements.

f. *Safeguards*. Data User shall use any and all appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.

g. *Data User's Agent*. Data User shall not disclose the Limited Data Set to any agent

or subcontractor of Data User except with the prior written consent of COTS. Data User shall ensure that any agents, including subcontractors, to whom it provides that Limited Data Set agrees in writing to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.

h. *Reporting*. Data User shall report to COTS within three (3) days of Data User becoming aware of any use or disclosure of the Limited Data Set in violation of this Agreement or applicable law.

i. *Cell Suppression Policy.* Data User must follow the following requirements related to cell value:

- No cell (e.g. admissions, discharges, patients, services, etc.) containing a value of 1 to 10 can be reported directly. A value of *zero* does not violate the minimum cell size policy.
- No cell can be reported that allows a value of 1 to 10 to be derived from other reported cells or information. For example, the use of percentages or other mathematical formulas that, in combination with other reported information, result in the display of a cell containing a value of 1 to 10 are prohibited.
- The cell suppression policy also applies to the reporting of excluded cases.

4. **Materials Breach, Enforcement and Termination.**

a. *Term*. This Agreement shall be effective as of the Effective Date, and shall continue until the Agreement is terminated in accordance with the provisions of Section 4(c).

b. *COTS's Rights of Access and Inspection*. From time to time upon reasonable notice, or upon a reasonable determination by COTS that Data User has breached this Agreement, COTS may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. The fact that COTS inspects, or fails to inspect, or has the right to inspect, Data User's facilities, systems and procedures does not relieve Data User or its responsibility to comply with this Agreement, nor does COTS's (1) failure to detect or (2) detection of, but failure to notify Data User or require Data User's remediation of, any unsatisfactory practices constitute acceptance of such practice or a waiver of COTS's enforcement or termination rights and obligations under this Section 4(b). This Section 4(b) shall survive termination of the Agreement.

c. *Termination*. This Agreement is effective as of the Effective Date and may be terminated by either party, with or without cause, upon ten (10) days written notice to the other party.

d. *Knowledge of Non-Compliance*. Any non-compliance by Data User with this Agreement or with HIPAA or the HIPAA Regulations automatically will be considered a breach or violation of a material term of this Agreement if Data User knew or reasonably should have known of such non-compliance and failed to immediately take reasonable steps to cure the non-compliance.

e. *Reporting*. Data User acknowledges and agrees that if COTS's efforts to cure any breach or end any violation are unsuccessful, and if termination of this Agreement is not feasible, COTS shall report to Provider such non-compliance by Data User of which COTS becomes aware, and Data User agrees that it shall not have or make any claim(s), whether at law, in equity, or under this Agreement, against COTS with respect to such report(s).

f. *Disposition of Records*. Upon termination of this Agreement, if PHI provided pursuant to this Agreement is retained in such a form by Data User to make the return of such PHI infeasible, Data User shall extend the protections of this Agreement to such PHI. Data

user shall return or destroy all other PHI that was provided to Data User pursuant to this Agreement. This section shall survive termination of this Agreement.

g. *Injunctions*. COTS and Data User agree that any violations of the provisions of this Agreement may cause irreparable harm to COTS. Accordingly, in addition to any other remedies available to COTS at law, in equity, or under this Agreement, in the event of any violation by Data User of any of the provisions of this Agreement, or any explicit threat thereof, COTS shall be entitled to an injunction or other decree of specific performance with respect to such violation or explicit threat thereof, without bond or other security being required. The parties' respective rights and obligations under this Section 4(g) shall survive termination of the Agreement.

5. **Miscellaneous Terms.**

a. *State Law*. Nothing in this Agreement shall be construed to require Data User to use or disclose the Limited Data Set without a written authorization from an individual who is a subject of the PHI from which the Limited Data Set was created, or written authorization from any other person, where such authorization would be required under state law for such use or disclosure.

b. *Amendment*. COTS and Data User agree that amendment of this Agreement may be required to ensure that COTS and Data User comply with corresponding amendments to the Provider Agreements regarding changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set.

c. *No Third Party Beneficiaries*. Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person or than COTS and Data User, and their respective successors and assigns, any rights, obligations, remedies, or liabilities.

d. *Ambiguities*. The parties agree that any ambiguity in this Agreement shall be resolved in favor or a meaning that complies and is consistent with the Provider Agreements, and/or applicable law protecting the privacy, security, and confidentiality of PHI and the Limited Data Set, including, but not limited to, HIPAA and the HIPAA Regulations.

e. *Primacy*. To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties, this Agreement shall control with respect to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement as of the Effective Date.

COTS	DATA USER:
_____	_____
Signature	*Signature*
_____	_____
Printed Name, Title	*Printed Name, Title*
_____	_____
Date	*Date*

DATE	TRACKING/WHAT HAS CHANGED?	STAFF MEMBER
1/25/2023	• Removed MREC and added Research Council chair, as the approval of comprehensive data request • Added backup plan if Research Council chair has conflict of interest	Giambri
11/16/2022	• Added Cell Suppression Policy to end of Trauma Registry Data Request Policy • Added Cell Suppression Policy to Exhibit E: Data Use Agreement & Exhibit F: Data Use Agreement for Government Employees • Added reminder about Cell Suppression Policy to Exhibit C: Expediated Data Request Form and Exhibit D: Comprehensive Data Request Form • Added November 2022 updated date	Kovach, Giambri & COTS Legal
5/26/2022	• Changed all references of Central Ohio Trauma System to COTS and updated website, email, and logo • Updated first sentence to match mission • Added Southeast and Southeast Central to describe members in paragraph 2 • Changed Executive Director to President • Updated member hospitals and date to May 2022 • Updated Exhibit A & D o Added the following: ▪ Scene Delay o Removed the following (no longer collected by COTS) ▪ Death Date & Death Time ▪ Autopsy Requested/Autopsy Performed ▪ Inter-facility Transfer EMS Run Sheet Present ▪ EMS Unit Number o Combined into one data element ▪ ED/Hospital Arrival Date ▪ ED/Hospital Arrival Time o Footnote added to the following: ▪ Scene Extraction (no data after 2022) ▪ Scene Delay (no data prior 2022) • Added Tracking Table	Giambri