



Number:	COTS-TRA-8
Title:	TRAUMA REGISTRY DATA REQUEST POLICY
Approved by:	COTS Board of Trustees (05/25/2021)
Initial Approval Date:	January 2002
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Next Review Date:	2027



## 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/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.

## EXHIBIT A: ALL COTS TRAUMA REGISTRY DATA ELEMENTS

### Elements Never Released

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

### Elements Released only as a Limited Data Set

Patient's Home City	ED/Hospital Arrival Date
Patient's Home County	Trauma Surgeon Arrival Date*
Patient's Home Zip Code	ED Discharge Order Written Date*
Alternative Home Residence	ED Discharge Date
Date of Birth	Procedure Start Date
Incident City^	Hospital Discharge Order Written Date*
Incident County^	Hospital Discharge Date
Incident Location Zip Code^	Injury Incident Date
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	

### Elements Released as De-Identified Data

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

^ 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

++ No Data prior to 2023

★ 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 January 2024. 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  
Hocking Valley Community Hospital, Logan, 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 Methodist Hospital, 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

***Members but not currently providing data to COTS:***

Genesis Coshocton Medical Center, Coshocton, Ohio  
Genesis Perry County Medical Center, Somerset, Ohio  
Holzer Gallipolis, Gallipolis, Ohio  
Holzer Medical Center – Jackson, Jackson, Ohio  
Holzer Meigs Emergency Department, Pomeroy, Ohio

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



**EXHIBIT C: EXPEDITED DATA REQUEST FORM**

<b>Requester Name &amp; Credentials:</b>	
<b>Title:</b>	
<b>Institution:</b>	
<b>Phone No:</b>	<b>Email:</b>
<b>What question is the data requester wanting to answer with COTS data?</b>	
<b>Dates of Inclusion of Data (from Month/Year through Month/Year)</b>	
<b>If data is to be stratified by subgroup, what subgroup? Example stratify sex by age. (Further clarification will be made with COTS)</b>	
<p><b>Please indicate how the data will be used. Check all that apply.</b></p> <p> <input type="checkbox"/> Own Department/Unit Use      <input type="checkbox"/> Own Hospital/Agency Use  <input type="checkbox"/> Department/Unit/Hosp/Agency use other than own: _____  <input type="checkbox"/> Educational Purposes      <input type="checkbox"/> Research  <input type="checkbox"/> Publication      <input type="checkbox"/> Public Policy  <input type="checkbox"/> Public Health      <input type="checkbox"/> Other: _____         </p>	
<p><b>Please indicate how the data will be stored. Check all that apply.</b></p> <p> <input type="checkbox"/> Double-lock file storage cabinet      <input type="checkbox"/> Password-protected desk-top computer  <input type="checkbox"/> Laptop with password protection &amp; anti-theft encryption software  <input type="checkbox"/> Other: _____         </p>	

*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](mailto:rgiambri@cotshealth.org)

**For COTS Use Only:**

**The following data will be released:**

**Approval for Release of Data:**

**Date:**

**Data Released By:**

**Date:**



# COTS

An affiliate of the Columbus Medical Association

## EXHIBIT D: COMPREHENSIVE DATA REQUEST FORM

<b>Title of Study or Project:</b>	
<b>Sponsor/Advisor if Applicable:</b>	
<b>Requester Name &amp; Credentials:</b>	<b>Title:</b>
<b>Institution:</b>	
<b>Institution Address:</b>	
<b>Phone No:</b>	<b>Email:</b>
<b>What question is the data requester wanting to answer with COTS data?</b>	
<b>Dates of Inclusion of Data (from Month/Year through Month/Year):</b>	
<b>Parameters for Data (i.e. ICD-10 diagnosis codes, mechanism of injuries, zip codes/counties)</b>	
<b>What is the target audience for the study/investigation?</b>	
<b>Indicate how results will be disseminated to the target audience:</b>	
<b>Is this project funded?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes, by: _____ In the amount of \$ _____	
<b>Please indicate how the data will be used. Check all that apply.</b> <input type="checkbox"/> Own Department/Unit Use <input type="checkbox"/> Own Hospital/Agency Use <input type="checkbox"/> Department/Unit/Hosp/Agency use other than own: _____ <input type="checkbox"/> Educational Purposes <input type="checkbox"/> Research <input type="checkbox"/> Publication <input type="checkbox"/> Public Policy <input type="checkbox"/> Public Health <input type="checkbox"/> Other: _____	
<i>Continued on next page</i>	
<b>Please indicate how the data will be stored. Check all that apply.</b> <input type="checkbox"/> Double-lock file storage cabinet <input type="checkbox"/> Password-protected desk-top computer <input type="checkbox"/> Laptop with password protection & anti-theft encryption software <input type="checkbox"/> 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.**

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

<input type="checkbox"/> Patient's Home City <input type="checkbox"/> Patient's Home County <input type="checkbox"/> Patient's Home Zip Code <input type="checkbox"/> Alternative Home Residence <input type="checkbox"/> Date of Birth <input type="checkbox"/> Injury Incident Date	<input type="checkbox"/> Incident City <input type="checkbox"/> Incident County <input type="checkbox"/> Incident Location Zip Code <input type="checkbox"/> EMS Dispatch Date to Scene/Transfer Hospital <input type="checkbox"/> EMS Arrival Date to Scene/Transfer Hospital	<input type="checkbox"/> EMS Left Date to Scene/Transfer Hospital <input type="checkbox"/> ED/Hospital Arrival Date <input type="checkbox"/> Trauma Surgeon Arrival Date <input type="checkbox"/> ED Discharge Order Written Date	<input type="checkbox"/> ED Discharge Date <input type="checkbox"/> Procedure Start Date <input type="checkbox"/> Hospital Discharge Order Written Date <input type="checkbox"/> Hospital Discharge Date  <p style="text-align: right;"><b>Continued on next page</b></p>
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**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](mailto: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.

#### 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 of 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.

#### 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 of 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
5/26/2022	<ul style="list-style-type: none"> <li>• Changed all references of Central Ohio Trauma System to COTS and updated website, email, and logo</li> <li>• Updated first sentence to match mission</li> <li>• Added Southeast and Southeast Central to describe members in paragraph 2</li> <li>• Changed Executive Director to President</li> <li>• Updated member hospitals and date to May 2022</li> <li>• Updated Exhibit A &amp; D <ul style="list-style-type: none"> <li>○ Added the following: <ul style="list-style-type: none"> <li>▪ Scene Delay</li> </ul> </li> <li>○ Removed the following (no longer collected by COTS) <ul style="list-style-type: none"> <li>▪ Death Date &amp; Death Time</li> <li>▪ Autopsy Requested/Autopsy Performed</li> <li>▪ Inter-facility Transfer EMS Run Sheet Present</li> <li>▪ EMS Unit Number</li> </ul> </li> <li>○ Combined into one data element <ul style="list-style-type: none"> <li>▪ ED/Hospital Arrival Date</li> <li>▪ ED/Hospital Arrival Time</li> </ul> </li> <li>○ Footnote added to the following: <ul style="list-style-type: none"> <li>▪ Scene Extraction (no data after 2022)</li> <li>▪ Scene Delay (no data prior 2022)</li> </ul> </li> </ul> </li> <li>• Added Tracking Table</li> </ul>	Giambri
1/25/2023	<ul style="list-style-type: none"> <li>• Removed MREC and added Research Council chair, as the approval of comprehensive data request</li> <li>• Added backup plan if Research Council chair has conflict of interest</li> <li>• Added January 2023 updated date</li> </ul>	Giambri
1/29/2024	<ul style="list-style-type: none"> <li>• Updated member facilities</li> <li>• Added Initial ED/Hospital GCS Total Score Exhibit A &amp; D</li> </ul>	Giambri
3/28/2024	<ul style="list-style-type: none"> <li>• Added Cover Page</li> <li>• Updated staff website link</li> <li>• Added Primary Trauma Service Type to Exhibit A &amp; D</li> </ul>	Giambri