



REGIONAL REGISTRY DATA REQUEST POLICY

INTRODUCTION

The Mission of the Central Ohio Trauma System (COTS) is to reduce injuries and save lives by improving and coordinating trauma care, emergency care, and disaster preparedness systems in Central Ohio. COTS' responsibility to patient care and patient confidentiality is paramount. This data request policy is intended to assist healthcare colleagues, injury prevention programs and community researchers in obtaining COTS Regional Trauma Registry data while assuring patient confidentiality.

The COTS Regional Trauma Registry has regional injury data dating to January 1999. Early years of the COTS Regional Trauma Registry are representative of a more minimal dataset than current years. COTS Regional 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 Regional Trauma Registry inclusion criteria, see the *COTS Data Elements Instruction Manual*.) The COTS Regional Trauma Registry captures demographic, clinical and outcome data from participating central Ohio hospitals. The intent of central Ohio hospitals and COTS in sharing such data is to improve trauma care, research and injury prevention efforts.

COTS DATA SETS

COTS Regional Trauma Registry has four data set options. No data from any of the following data request options is ever provided that would directly identify a single patient or institution.

- 1) **Individual Data Elements:** The individual data elements option allows the requestor to choose from available data elements in the COTS Regional Trauma Registry. All COTS Regional Trauma Registry data elements are listed in *EXHIBIT A*. Data elements that are not available to be released are indicated in italics. Indirect identifiers that may be released are indicated with an asterisk. No requestor shall have access to the entire set of individual data elements; only those data elements specifically requested will be released. Any member of the public may request individual data elements.

The COTS **Formal Data Request Application Form** (*EXHIBIT E*) must be used to specify the individual data elements that are wanted from this data set. The Formal Data Request Application includes a Data Use Agreement.

- 2) **COTS Member Data Set:** The COTS Member Data Set includes a select set of data elements from the Individual Data Elements that has been determined by COTS to represent the minimum necessary information needed for most data request purposes of COTS member-institutions. *EXHIBIT C* documents the list of data elements in the COTS Member Data Set. Any data element from this data set that is not necessary for the project at hand must be disclosed by the data requestor so that COTS can exclude it prior to the data release.

Only individuals from COTS member-institutions ("COTS members") can request the COTS Member Data Set. A COTS member-institution is one who directly contributes trauma patient data to the COTS Regional Trauma Registry. A list of COTS member-institutions is in *EXHIBIT B*. COTS members shall use the **Abbreviated Data Request Form** (*EXHIBIT F*) to request the COTS Member Data Set. A Data Use Agreement is required to receive data from the COTS Member Data Set.

- 3) **COTS Basic Data Set:** The COTS Basic Data Set includes only those data elements from the COTS Regional Trauma Registry that are indistinguishable among trauma cases. Data elements available through the COTS Basic Data Set are listed in *EXHIBIT D*.

Any member of the public may request data from the COTS Basic Data Set via the COTS *Abbreviated Data Request Form* (*EXHIBIT F*). Use of the Basic Data Set requires a Data Use Agreement.

- 4) **COTS Aggregate Data Set:** COTS data is available in an aggregate data set. An aggregate data set provides summarized information to answer a specific question. Any member of the public may request aggregate data from COTS via the COTS *Abbreviated Data Request Form* (*EXHIBIT F*). Use of COTS' aggregate data does not require a Data Use Agreement.

Table 1 describes some differences in COTS' available data sets.

ENGAGEMENT IN RESEARCH

The Office of Human Research Protections (OHRP) under the U.S. Department of Health & Human Services (DHHS) considers "human subjects research" to be that which involves identifiable private information. "Human subjects research" requires either: (1) review by an Institutional Review Board (IRB) with a Federal Wide Assurance (FWA), or (2) a determination that the research is exempt from review (exemptions are usually determined by an Institutional Review Board representative). Data which is coded (assigned codes which are not derived from other identifiers) is not necessarily considered to be human-subjects research if certain conditions are met. (See *Guidance on Research Involving Coded Private Information or Biological Specimens*, Department of Health & Human Services, Office for Human Research Protections, August 2004).

Researchers are responsible for seeking their institution's IRB (or Privacy Board, if applicable) approval prior to requesting COTS data if they are requesting data with identifiers. A copy of the institution's IRB approval must be provided before COTS can release data from the Individual Data Elements (including the Core Module).

If COTS wishes to participate in the research (e.g. a COTS employee serves as an investigator or co-investigator), activities must be in accordance with OHRP guidance on engagement in research. In most cases, this will either require that codes not be retained once the research begins or that IRB approval be obtained for COTS' role. Individuals from COTS' member organizations act under the authority of their institution's IRB or Privacy Board.

COTS acknowledges and accepts its responsibilities for protecting the confidentiality of patients, **however the responsibility for the establishment and maintenance of acceptable ethical practice in research always remains with the individual investigator.**

DATA OWNERSHIP

COTS Regional Trauma Registry data is owned by COTS. Likewise, each institution that submits data to COTS “owns” their individual institutional data housed at COTS. Individuals who submit their institutional data to COTS can request their data or a subset of it back at any time from COTS via a simple written request to the COTS Registrar. Similarly, verified trauma centers’ trauma program managers may obtain any of their own institution-specific data upon written request for uses related to process improvement.

TABLE 1: Comparison of COTS Data Sets

	Individual Data Elements	COTS Member Data Set	Core Data Set	Aggregate Data Set
How many data elements are in each data set?	Approximately 99 data elements; only those data elements that are specifically requested will be released	Approximately 87 data elements	Approximately 73 data elements	Only the number of data elements specifically requested
How many indirect identifiers are included? (“Identifiers” in COTS Database are data elements such as birthdates, zip codes, county of injury, etc.)	Only those indirect identifiers that are specifically requested will be released	Includes some indirect identifiers	Includes no indirect identifiers	Includes no indirect identifiers
For what purpose can the data be requested	Research, public health & healthcare operations	Research, public health & healthcare operations	Research, public health & healthcare operations	Research, public health, healthcare operations, & media inquiries
Which COTS form is used to request data?	Formal Data Request Application Form	Abbreviated Data Request Form	Abbreviated Data Request Form	Abbreviated Data Request Form
Is a Data Use Agreement required?	Yes	Yes	Yes	No
Who ultimately approves/signs off on the data request?	COTS Data Request Review Committee & Committee Chair	The COTS member-institution’s rep on the COTS Board & COTS’ Executive Director	COTS’ Executive Director	COTS’ Executive Director or his/her designee
Is proof of institutional IRB required?	Yes, if project meets U.S. DHHS definition of Human Subjects Research (45 CFR 46)	Yes, if project meets U.S. DHHS definition of Human Subjects Research (45 CFR 46)	No	No
How long may the request take to go through the COTS data approval process?	Up to 60 days	Up to 45 days	Up to two weeks [^]	Hours to days [^]

[^]Rapidity in the provision of data is dependent upon the availability of the COTS Registrar

DATA REQUESTS TO COTS

Data requests must be submitted in writing to COTS. COTS data is requested via one of two processes:

- COTS Formal Data Request Application Form (*EXHIBIT E*)
- COTS Abbreviated Data Request Form (*EXHIBIT F*)

Data requests by those other than COTS institutional members may be subject to a data-release fee, especially if the reason for the request involves sponsor-supported research. Fees are determined on a case-by-case basis and are set by the COTS Data Request Review Committee.

Data request applications should be submitted to the COTS Trauma Registrar, 431 East Broad Street, Columbus, Ohio 43215. For more information, inquires can be made to phone # (614) 240-7419, Extension 3, or rgiambri@goodhealthcolumbus.org.

Occasionally COTS receives data requests that involve an individual hospital's data. The data requestor must submit in writing why they are requesting an individual hospital's data. Data requestors wanting an individual hospital's data must also still complete either the COTS Formal Data Request Application Form or Abbreviated Data Request Application Form. The respective hospital CEO or COO must sign the ***CEO/COO Data Release Form for Hospital-Specific Data (EXHIBIT G)*** in order for COTS to release an individual hospital's data. COTS will correspond with the respective hospital CEO or COO regarding signature on the *CEO/COO Data Release Form for Hospital-Specific Data*. *NOTE:* The exception to this is described in the previous section, *Data Ownership*.

COTS FORMAL DATA REQUEST APPLICATION PROCESS

The COTS Formal Data Request Application process and Form are used when:

- A data requestor wants more than the COTS Basic Data Set or Aggregate Data Set AND he/she is not an individual from a COTS member-institution
- A data requestor from a COTS member-institution wants individual data elements from the COTS Regional Trauma Registry beyond those included in any of the other available data sets

The Formal Data Request Application Form includes:

- Title of the study or project
- The principle investigator's or project director's name, credentials, title, institution & contact information
- The name of a sponsor or advisor if applicable
- Whether a similar data request was submitted to another registry, and if so, which one
- Whether this or a similar data request was previously denied to this requestor by COTS
- The question that the data request is trying to answer
- Dates for the inclusion of data
- Whether the data is to be stratified by a subgroup
- Indications of how the data will be used
- Safeguards for maintaining data confidentiality
- The target audience for the study/investigation results
- How the results will be disseminated to the target audience
- Whether the project is funded by a third-party sponsor and if so, for how much
- Any individual COTS data elements being requested
- An indication of why these elements are the minimum necessary to complete the project

- Affirmation that COTS will be acknowledged as the source for the data, and that COTS will receive a written summary at the end of the project
- The name and contact info of the person completing the application
- The signature of the principle investigator or project director

A request for COTS data using the Formal Data Request Application Form warrants review and approval via the COTS Data Request Review Committee. The COTS Data Request Review Committee consists of the COTS Executive Committee, a representative from the COTS Regional Trauma Registry Committee and COTS' legal counsel.

The COTS Data Request Review Committee meets as needed based on proposal submission. Data Request Review Committee members receive the proposals to be reviewed through COTS one to two weeks prior to meeting. In-person meetings will not occur with greater frequency than once every two months, however members may also conduct business via email or teleconference if considered to be necessary by the Committee.

If the proposal is for a study that constitutes "human subjects research" as defined by the OHRP and the Data Request Review Committee approves the proposal, the Principal Investigator must provide a copy of his or her institution's IRB approval before the data will be released. COTS can provide a letter to the Principal Investigator indicating agreement to release the data, contingent upon receipt of the IRB approval.

COTS ABBREVIATED DATA REQUEST APPLICATION PROCESS

COTS Abbreviated Data Request process and Form (*EXHIBIT F*) may be used when:

- The request is made by an individual from a COTS member-institution AND the COTS Member Data Set is desired
- The requestor wants the Basic Data Set or the Aggregate Data Set

The Abbreviated Data Request Form includes:

- The data requestor's name, title, institution & contact information
- Whether a similar data request was submitted to another registry, and if so, which one
- The question that the data request is trying to answer
- Dates for the inclusion of data
- Whether the data is to be stratified by a subgroup
- Indications of how the data will be used
- Safeguards for maintaining data confidentiality
- Which COTS Data Set is being requested
- Affirmation that COTS will be acknowledged as the source for the data, and that COTS will receive a written summary at the end of the project
- Signature of the data requestor

DATA REQUEST RESPONSE FROM COTS

Data requestors will receive notification about their request from COTS Executive Director via the U.S. Postal Service or e-mail within sixty days. Notification will include one of the following responses to the data request.

- “Approved:” The data request is acceptable and the data will be released.
- “Approved Conditionally:” The proposal is worthwhile but some minor additions, clarifications or modifications are necessary before final approval. Once these changes are submitted, the request will be approved.
- “Deferred:” The proposal is not complete or concise enough for the Data Request Review Committee or Executive Director to make a decision. The researcher will be notified of the action and reason for the action, and may resubmit the proposal.
- “Disapproved:” The proposal is disapproved because it:
 - Is inconsistent with COTS’ Mission;
 - Produces data that breeches patient-confidentiality;
 - Violates the HIPAA Privacy Rule;
 - Compromises a member-institution’s rights to data;
 - Remains uncompleted for 60 days after a previous “Deferred” decision by COTS;
 - Is repetitive of a segment of COTS community injury report;
 - Induces a financially competitive situation with a potential grant sponsor that may affect the present or future viability of COTS; or
 - Is inconsistent with the guidelines established for COTS Formal Data Request Application Form or COTS Abbreviated Data Request Form.

Prior to release of data for “Approved” projects, COTS will ascertain confidentiality of the data set with regards to hospitals and patients. If the data isolates a single hospital or patient such that confidentiality is breeched, the data request will be denied.

DATA SOURCE DISCLOSURE

Data requestors must agree to cite the COTS Regional Trauma Registry as the source of the data to project-related planning sessions or performance improvement committees. Any publications related to this research project must give credit to the Central Ohio Trauma System Regional Registry for the raw data. Copies of any public or professional articles utilizing COTS data should be forwarded to COTS upon publication.

DATA RECEIPT

Once a data request is approved, data will be released to the requestor within 30 days. Data will be sent via e-mail to the requestor in a password-protected Excel spreadsheet. The password will be provided in a phone conversation between the requestor and COTS registrar. Data files too large to be e-mailed will be copied onto a CD which will be certified-mailed via the USPS, with required signature-confirmation upon receipt by the requestor, or the requestor can pick up the completed CD from COTS.

Originally developed January 2002. Updated April 2003, October 2003, March 2004, November 200, November 2006, May 2009 & August 2009.

Most recent Update Approved by the COTS Board of Trustees on August 25, 2009

EXHIBIT A: ALL COTS REGIONAL TRAUMA REGISTRY DATA ELEMENTS

<i>Trauma Number</i>	First Systolic Blood Pressure at Hospital
<i>Institute Number</i>	First GCS Eye Component at Hospital
<i>Unique Patient Admission Number</i>	First GCS Verbal Component at Hospital
Gender	First GCS Motor Component at Hospital
Date of Birth*	First GCS Assessment Qualifier at Hospital
Age	ED Intubation
Race	ED CPR
Zip Code of Residence*	ED Needle Decompression or Chest Tube Insertion
Demographic Injury Location (County/State)	ED Spinal Immobilization
Cause of Injury E-Code	Alcohol Screening
Injury Date*	Toxicology Screening
Protective Devices	Toxicology Screening Results
Protective Devices Apply	Pre-Existing Conditions (Comorbids)
Place of Injury	ED Head CT
Work Related Injury	ED Abdominal/Pelvic CT
Scene EMS Run Sheet Present	ED Diagnostic Peritoneal Lavage
Mode of Transport	ED Abdominal Ultrasound
EMS Run Sheet Present	ED Discharge Time
<i>EMS Provider Name</i>	ED Discharge Date*
<i>EMS Run Report Number</i>	ED Disposition
Pre-Hospital Dispatch Time to Scene	<i>ED Destination</i>
Pre-Hospital Dispatch Date to Scene*	Hospital Length of Stay
Pre-Hospital Time Arrived at Scene	ICU Length of Stay
Pre-Hospital Date Arrived at Scene*	Ventilator Support Length of Stay
Pre-Hospital Time Left Scene	Discharge Status
Pre-Hospital Date Left Scene*	Autopsy Performed
Scene Extrication	Organ/Tissue Granted
First Scene Glasgow Coma Score (GCS) Eye Component	Organ/Tissue Taken
First Scene GCS Verbal Component	Hospital Discharge Disposition
First Scene GCS Motor Component	<i>Hospital Discharge Destination</i>
First Scene GCS Assessment Qualifier	Hospital Discharge Date*
Scene CPR	Hospital Discharge Time
Scene Intubation	Principle Payment
Scene Fluids	Billed Hospital Charges
Scene Needle Chest Decompression or Chest Tube Insertion	Complications
Scene Immobilization	Functional Outcome Measure (FOM): Feeding
Scene Triage Codes (Adult and Pediatric)	FOM: Locomotion
Hospital Arrival Source	FOM: Expression
Hospital Transfer	Diagnosis ICD-9 Code
<i>Transfer from Hospital</i>	Abbreviated Injury Scale (AIS) Code
Emergency Department (ED) Arrival Time	Abbreviated Injury Scale (AIS) Severity Score
ED Arrival Date*	AIS Body Region
Hospital Arrival Time	Injury Severity Score (ISS)
Hospital Arrival Date*	Procedure Codes
Trauma Type	Procedure ICD-9
Trauma Alert Called	Procedure Location
Admitting Service	Procedure Results
First Pulse Rate at Hospital	Procedure Start Date*
First Respiratory Rate at Hospital	Procedure Start Time
First Temperature at Hospital	

Italics denote individual data elements that will not be released.
An asterisk (*) denotes an indirect identifier that can be released.

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EXHIBIT B: COTS MEMBER INSTITUTIONS

The following are COTS member-institutions as of August 2009. A COTS member-institution is one who directly contributes trauma patient data to the COTS Regional Trauma Registry.

Adena Regional Medical Center, Chillicothe, Ohio
Berger Health System, Circleville, Ohio
Coshocton County Memorial Hospital, Coshocton, Ohio
Doctors Hospital, Columbus, Ohio
Dublin Methodist Hospital, Dublin, Ohio
Fairfield Medical Center, Lancaster, Ohio
Genesis Healthcare System, Zanesville, Ohio
Grady Memorial Hospital, Delaware, Ohio
Grant Medical Center, Columbus, Ohio
Knox Community Hospital, Mt. Vernon, Ohio
Madison County Hospital, London, Ohio
Marietta Memorial Hospital, Marietta, Ohio
Marion General Hospital, Marion, Ohio
Memorial Hospital of Union County, Marysville, Ohio
Morrow County Hospital, Mt. Gilead, Ohio
Mount Carmel East, Columbus, Ohio
Mount Carmel New Albany Surgical Hospital, New Albany, Ohio
Mount Carmel St. Ann's, Westerville, Ohio
Mount Carmel West, Columbus, Ohio
Nationwide Children's Hospital, Columbus, Ohio
The Ohio State University Medical Center, Columbus, Ohio
The Ohio State University Hospital East, Columbus, Ohio
Riverside Methodist Hospital, Columbus, Ohio
Southeastern Ohio Regional Medical Center, Cambridge, Ohio

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EXHIBIT C: COTS MEMBER DATA SET

(NOTE: Must be an individual from a COTS member-institution to have access to this data set)

Gender	First GCS Eye Opening Score at Hospital
Birth Date (Year Only)	First GCS Verbal Score at Hospital
Race	First GCS Motor Score at Hospital
Residence Zip Code	First GCS Assessment Qualifies at Hospital
Demographic Injury Location	ED Intubation
Cause of Injury E Code	ED CPR
Injury Date	ED Spinal Immobilization
Protective Devices	Alcohol Screening*
Protective Devices Apply	Toxicology Screening*
Place of Injury	Toxicology Screening Results*
Work Related Injuries	Pre-Existing Conditions (Comorbids)
Scene EMS Run Sheet Present	ED Head Computerized Topography (CT) Scan
Mode of Transport	ED Abdominal/Pelvis CT Scan
EMS Run Present	ED Diagnostic Peritoneal Lavage
Pre-Hospital Dispatch Time to Scene	ED Abdominal Ultrasound
Pre-Hospital Dispatch Date to Scene	ED Discharge Time
Pre-Hospital Time Arrived at Scene	ED Discharge Date
Pre-Hospital Date Arrived at Scene	ED Disposition
Pre-Hospital Time Left Scene	Hospital Length of Stay
Pre-Hospital Date Left Scene	Intensive Care Unit (ICU) Length of Stay
Scene Extrication	Ventilator Support Days in Hospital
First Scene Glasgow Coma Score (GCS)Eye opening Score	Discharge Status
First Scene GCS Verbal Score	Autopsy Performed
First Scene GCS Motor Score	Organ/Tissue Donation Granted
EMS GCS Assessment Qualifier	Organ/Tissue Donation Taken
Scene CPR	Hospital Discharge Disposition
Scene Intubation	Hospital Discharge Time
Scene Fluids	Hospital Discharge Date
Scene Needle Chest Decompression/Chest Tube Insertion	Principle Payment
Scene Immobilization	Billed Hospital Charges*
Hospital Arrival Source	Complications*
Hospital Transfer	Funtional Outcome Measure (FOM): Feeding Upon Discharge*
Emergency Department (ED) Arrival Time	FOM: Locomotion Upon Discharge*
ED Arrival Date	FOM: Expression Upon Discharge*
Hospital Arrival Time	Diagnosis ICD-9 Code
Hospital Arrival Date	Abbreviated Injury Scale (AIS) Code
Trauma Type	AIS Severity Score
Trauma Alert Called	AIS Body Region
Admitting Service	Injury Severity Score (ISS)
First Pulse Rate at Hospital	Procedure Code
First Respiratory Rate at Hospital	Procedure ICD-9 Codes
First Temperature at Hospital	Procedure Location
First Systolic Blood Pressure at Hospital	Procedure Results
	Operating Room (OR) Procedure Start Date
	OR Procedure Start Time

*Data is incomplete

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EXHIBIT D: COTS BASIC DATA SET

Gender	First GCS Eye Opening Score at Hospital
Age (≥ 90 is single category)	First GCS Verbal Score at Hospital
Race	First GCS Motor Score at Hospital
Cause of Injury E Code	First GCS Assessment Qualifier at Hospital
Injury Date (Year Only)	ED Intubation
Protective Devices	ED CPR
Protective Devices Apply	ED Spinal Immobilization
Place of Injury	Alcohol Screening*
Work Related Injuries	Toxicology Screening*
Scene EMS Run Sheet Present	Toxicology Screening Results*
Mode of Transport	Pre-Existing Conditions(Co-morbids)
EMS Run Sheet Present	ED Head Computerized Topography (CT) Scan
Pre-Hospital Dispatch Date to Scene (Year Only)	ED Abdominal/Pelvis CT Scan
Pre-Hospital Date Arrived at Scene (Year Only)	ED Diagnostic Peritoneal Lavage
Pre-Hospital Date Left Scene (Year Only)	ED Abdominal Ultrasound
Scene Extrication	ED Discharge Time
First Scene Glasgow Coma Score (GCS) Eye Opening Score	ED Discharge Date (Year Only)
First Scene GCS Verbal Score	ED Disposition
First Scene GCS Motor Score	Hospital Length of Stay
EMS GCS Assessment Qualifier	Intensive Care Unit (ICU) Length of Stay
Scene CPR	Ventilator Support Days in Hospital
Scene Intubation	Discharge Status
Scene Fluids	Autopsy Performed
Scene Needle Chest Decompression or Chest Tube Insertion	Organ/Tissue Donation Granted
Scene Immobilization	Organ/Tissue Donation Taken
Hospital Arrival Source	Hospital Discharge Disposition
Hospital Transfer	Hospital Discharge Time
Emergency Department (ED) Arrival Time	Hospital Discharge Date (Year Only)
ED Arrival Date (Year Only)	Principle Payment
Hospital Arrival Time	Functional Outcome Measure (FOM): Feeding Upon Discharge*
Hospital Arrival Date (Year Only)	FOM: Locomotion Upon Discharge*
Trauma Type	FOM: Expression Upon Discharge*
Trauma Alert Called	Diagnosis ICD-9 Code
Admitting Service	Abbreviated Injury Scale (AIS) Code
First Pulse Rate at Hospital	AIS Severity Score
First Respiratory Rate At Hospital	AIS Body Region
First Temperature at Hospital	Injury Severity Score (ISS)
First Systolic Blood Pressure at Hospital	

**Data is incomplete*

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Central Ohio
Trauma System

EXHIBIT E: FORMAL DATA REQUEST APPLICATION FORM

The Data Requestor shall complete the following: Please type or print. If there is more information to be provided than the form allows, please use a separate piece of paper.

1) Title of Study or Project	
2) Principle Investigator (PI) / Project Director (PD) Name	
3) PI/PD Credentials	
4) PI/PD Title	
5) PI/PD Institution	
6) PI/PD Address	
7) PI/PD Phone Number	
8) PI/PD E-mail Address	
9) Sponsor / Advisor if Applicable	
10) Has this or a similar data request been previously denied by COTS? If yes, when?	<input type="checkbox"/> NO <input type="checkbox"/> YES, on (list date):

11) Has this or a similar data request been submitted to another registry?	<input type="checkbox"/>
<input type="checkbox"/> NO <input type="checkbox"/> YES <input type="checkbox"/> Ohio Trauma Registry <input type="checkbox"/> Hospital Registry <input type="checkbox"/> OTHER:	
12) What question does the PI/PD want to answer with COTS data?	
13) Dates for inclusion of data (From Month & Year / Through Month/Year)	
14) If the data is to be stratified by a subgroup, what is the subgroup?	
15) Please indicate how the data will be used. Check all that apply. <ul style="list-style-type: none"> <input type="checkbox"/> Own Department/Unit use <input type="checkbox"/> Own Hospital/Agency use <input type="checkbox"/> Department/Unit/Hospital/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: _____ 	
16) What safeguards are in place for maintaining the confidentiality of data? <ul style="list-style-type: none"> <input type="checkbox"/> Double-lock file storage cabinet <input type="checkbox"/> Password-protected desk-top computer <input type="checkbox"/> Laptop with password protection and anti-theft encryption hardware <input type="checkbox"/> Other: _____ 	
17) What is the target audience for the study / investigation?	
18) Indicate how results will be disseminated to the target audience.	
19) Is the project funded?	<input type="checkbox"/> NO <input type="checkbox"/> YES by _____ In the AMOUNT of \$ _____

20) If the request indicated in Section #20 is for Individual Data Elements from the Limited Data Set, please check the specific data elements being requested.

<input type="checkbox"/> Gender	<input type="checkbox"/> First GCS Eye Component at Hospital
<input type="checkbox"/> Date of Birth*	<input type="checkbox"/> First GCS Verbal Component at Hospital
<input type="checkbox"/> Age	<input type="checkbox"/> First GCS Motor Component at Hospital
<input type="checkbox"/> Race	<input type="checkbox"/> First GCS Assessment Qualifier at Hospital
<input type="checkbox"/> Zip Code of Residence*	<input type="checkbox"/> ED Intubation
<input type="checkbox"/> Demographic Injury Location (County/State)	<input type="checkbox"/> ED CPR
<input type="checkbox"/> Cause of Injury E-Code	<input type="checkbox"/> ED Needle Decompression or Chest Tube Insertion
<input type="checkbox"/> Injury Date*	<input type="checkbox"/> ED Spinal Immobilization
<input type="checkbox"/> Protective Devices	<input type="checkbox"/> Alcohol Screening*
<input type="checkbox"/> Protective Devices Apply	<input type="checkbox"/> Toxicology Screening*
<input type="checkbox"/> Place of Injury	<input type="checkbox"/> Toxicology Screening Results
<input type="checkbox"/> Work Related Injury	<input type="checkbox"/> Pre-Existing Conditions (Comorbids)
<input type="checkbox"/> Scene EMS Run Sheet Present	<input type="checkbox"/> ED Head CT
<input type="checkbox"/> Mode of Transport	<input type="checkbox"/> ED Abdominal/Pelvic CT
<input type="checkbox"/> EMS Run Sheet Present	<input type="checkbox"/> ED Diagnostic Peritoneal Lavage
<input type="checkbox"/> Pre-Hospital Dispatch Time to Scene	<input type="checkbox"/> ED Abdominal Ultrasound
<input type="checkbox"/> Pre-Hospital Dispatch Date to Scene*	<input type="checkbox"/> ED Discharge Time
<input type="checkbox"/> Pre-Hospital Time Arrived at Scene	<input type="checkbox"/> ED Discharge Date*
<input type="checkbox"/> Pre-Hospital Date Arrived at Scene*	<input type="checkbox"/> ED Disposition
<input type="checkbox"/> Pre-Hospital Time Left Scene	<input type="checkbox"/> Hospital Length of Stay
<input type="checkbox"/> Pre-Hospital Date Left Scene*	<input type="checkbox"/> ICU Length of Stay
<input type="checkbox"/> Scene Extrication	<input type="checkbox"/> Ventilator Support Length of Stay
<input type="checkbox"/> First Scene Glasgow Coma Score (GCS) Eye Component	<input type="checkbox"/> Discharge Status
<input type="checkbox"/> First Scene GCS Verbal Component	<input type="checkbox"/> Autopsy Performed
<input type="checkbox"/> First Scene GCS Motor Component	<input type="checkbox"/> Organ/Tissue Granted
<input type="checkbox"/> First Scene GCS Assessment Qualifier	<input type="checkbox"/> Organ/Tissue Taken
<input type="checkbox"/> Scene CPR	<input type="checkbox"/> Hospital Discharge Disposition
<input type="checkbox"/> Scene Intubation	<input type="checkbox"/> Hospital Discharge Date*
<input type="checkbox"/> Scene Fluids	<input type="checkbox"/> Hospital Discharge Time
<input type="checkbox"/> Scene Needle Chest Decompression or Chest Tube Insertion	<input type="checkbox"/> Principle Payment
<input type="checkbox"/> Scene Immobilization	<input type="checkbox"/> Billed Hospital Charges
<input type="checkbox"/> Scene Triage Codes (Adult and Pediatric)	<input type="checkbox"/> Complications
<input type="checkbox"/> Hospital Arrival Source	<input type="checkbox"/> Functional Outcome Measure (FOM): Feeding
<input type="checkbox"/> Hospital Transfer	<input type="checkbox"/> FOM: Locomotion
<input type="checkbox"/> Emergency Department (ED) Arrival Time	<input type="checkbox"/> FOM: Expression
<input type="checkbox"/> ED Arrival Date*	<input type="checkbox"/> Diagnosis ICD-9 Code
<input type="checkbox"/> Hospital Arrival Time	<input type="checkbox"/> Abbreviated Injury Scale (AIS) Code
<input type="checkbox"/> Hospital Arrival Date*	<input type="checkbox"/> Abbreviated Injury Scale (AIS) Severity Score
<input type="checkbox"/> Trauma Type	<input type="checkbox"/> AIS Body Region
<input type="checkbox"/> Trauma Alert Called	<input type="checkbox"/> Injury Severity Score (ISS)
<input type="checkbox"/> Admitting Service	<input type="checkbox"/> Procedure Codes
<input type="checkbox"/> First Pulse Rate at Hospital	<input type="checkbox"/> Procedure ICD-9
<input type="checkbox"/> First Respiratory Rate at Hospital	<input type="checkbox"/> Procedure Location
<input type="checkbox"/> First Temperature at Hospital	<input type="checkbox"/> Procedure Results
<input type="checkbox"/> First Systolic Blood Pressure at Hospital	<input type="checkbox"/> Procedure Start Date*
	<input type="checkbox"/> Procedure Start Time

* Denotes an indirect identifier that may be released in the Limited Data Set

21) Describe why the data elements selected from Section #21 are the minimum required for the project	
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22) Please acknowledge the following:

- Central Ohio Trauma System will be acknowledged as source for information in any materials being presented and/or published.*
- Central Ohio Trauma System will receive a project summary at the completion of the project.*

23) Notes or other comments	
-----------------------------	--

24) Name of person completing this form	
---	--

25) Title of person in # 25	
-----------------------------	--

26) Contact number for #25	
----------------------------	--

27) Signature of PI/PD	
------------------------	--

28) Date when signed	
----------------------	--

COTS Data Request Applications should be submitted to Central Ohio Trauma System, 431 East Broad Street, Columbus, Ohio 43215 or to rgiambri@goodhealthcolumbus.org.

FOR COTS USE ONLY:

Approval for Release of Data: _____ Date: _____

Data Released By: _____ Date: _____



EXHIBIT F: ABBREVIATED DATA REQUEST FORM

The Data Requestor shall complete the following: Please type or print. If there is more information to be provided than the form allows, please use a separate piece of paper.

1) Data Requestor's Name	
2) Data Requestor's Title	
3) Data Requestor's Institution	
4) Data Requestor's Phone Number	
5) Data Requestor's E-mail Address	

6) Has this or a similar data request been submitted to another registry?

- YES:
 Ohio Trauma Registry
 Hospital Registry
 OTHER: _____
 NO

7) What question is the Data Requestor wanting to answer with COTS data?	
8) Dates for inclusion of data (From Month/Year / Through Month/Year)	
9) If the data is to be stratified by a subgroup, what is the subgroup?	

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

- Own Department/Unit use
 Own Hospital/Agency use
 Department/Unit/Hospital/Agency use other than own: _____
 Educational purposes
 Research
 Publication
 Public Policy
 Public Health
 Other: _____

11) What safeguards are in place for maintaining the confidentiality of data?

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

12) Select the COTS Data Set Requested

- COTS Member Data Set (Must be from a COTS member-institution to get this data set): See *EXHIBIT C*
- Basic Data Set: See *EXHIBIT D*
- Aggregate Data Set

13) Please acknowledge the following:

- Central Ohio Trauma System will be acknowledged as source for information in any materials being presented and/or published.*
- Central Ohio Trauma System will receive a project summary at the completion of the project.*

14) Signature of Data Requestor

15) Date when signed

COTS Data Request Applications should be submitted to Central Ohio Trauma System, 431 East Broad Street, Columbus, Ohio 43215 or to rgiambri@goodhealthcolumbus.org.

FOR COTS USE ONLY:

Approval for Release of Data: _____ Date: _____

Data Released By: _____ Date: _____

Any data element that is not necessary for the project at hand must be disclosed by the data requestor so that COTS can exclude it prior to the data release.

Please indicate the specific data elements being requested.

<input type="checkbox"/> Gender	<input type="checkbox"/> First GCS Eye Component at Hospital
<input type="checkbox"/> Date of Birth*	<input type="checkbox"/> First GCS Verbal Component at Hospital
<input type="checkbox"/> Age	<input type="checkbox"/> First GCS Motor Component at Hospital
<input type="checkbox"/> Race	<input type="checkbox"/> First GCS Assessment Qualifier at Hospital
<input type="checkbox"/> Zip Code of Residence*	<input type="checkbox"/> ED Intubation
<input type="checkbox"/> Demographic Injury Location (County/State)	<input type="checkbox"/> ED CPR
<input type="checkbox"/> Cause of Injury E-Code	<input type="checkbox"/> ED Needle Decompression or Chest Tube Insertion
<input type="checkbox"/> Injury Date*	<input type="checkbox"/> ED Spinal Immobilization
<input type="checkbox"/> Protective Devices	<input type="checkbox"/> Alcohol Screening*
<input type="checkbox"/> Protective Devices Apply	<input type="checkbox"/> Toxicology Screening*
<input type="checkbox"/> Place of Injury	<input type="checkbox"/> Toxicology Screening Results
<input type="checkbox"/> Work Related Injury	<input type="checkbox"/> Pre-Existing Conditions (Comorbids)
<input type="checkbox"/> Scene EMS Run Sheet Present	<input type="checkbox"/> ED Head CT
<input type="checkbox"/> Mode of Transport	<input type="checkbox"/> ED Abdominal/Pelvic CT
<input type="checkbox"/> EMS Run Sheet Present	<input type="checkbox"/> ED Diagnostic Peritoneal Lavage
<input type="checkbox"/> Pre-Hospital Dispatch Time to Scene	<input type="checkbox"/> ED Abdominal Ultrasound
<input type="checkbox"/> Pre-Hospital Dispatch Date to Scene*	<input type="checkbox"/> ED Discharge Time
<input type="checkbox"/> Pre-Hospital Time Arrived at Scene	<input type="checkbox"/> ED Discharge Date*
<input type="checkbox"/> Pre-Hospital Date Arrived at Scene*	<input type="checkbox"/> ED Disposition
<input type="checkbox"/> Pre-Hospital Time Left Scene	<input type="checkbox"/> Hospital Length of Stay
<input type="checkbox"/> Pre-Hospital Date Left Scene*	<input type="checkbox"/> ICU Length of Stay
<input type="checkbox"/> Scene Extrication	<input type="checkbox"/> Ventilator Support Length of Stay
<input type="checkbox"/> First Scene Glasgow Coma Score (GCS) Eye Component	<input type="checkbox"/> Discharge Status
<input type="checkbox"/> First Scene GCS Verbal Component	<input type="checkbox"/> Autopsy Performed
<input type="checkbox"/> First Scene GCS Motor Component	<input type="checkbox"/> Organ/Tissue Granted
<input type="checkbox"/> First Scene GCS Assessment Qualifier	<input type="checkbox"/> Organ/Tissue Taken
<input type="checkbox"/> Scene CPR	<input type="checkbox"/> Hospital Discharge Disposition
<input type="checkbox"/> Scene Intubation	<input type="checkbox"/> Hospital Discharge Date*
<input type="checkbox"/> Scene Fluids	<input type="checkbox"/> Hospital Discharge Time
<input type="checkbox"/> Scene Needle Chest Decompression or Chest Tube Insertion	<input type="checkbox"/> Principle Payment
<input type="checkbox"/> Scene Immobilization	<input type="checkbox"/> Billed Hospital Charges
<input type="checkbox"/> Scene Triage Codes (Adult and Pediatric)	<input type="checkbox"/> Complications
<input type="checkbox"/> Hospital Arrival Source	<input type="checkbox"/> Functional Outcome Measure (FOM): Feeding
<input type="checkbox"/> Hospital Transfer	<input type="checkbox"/> FOM: Locomotion
<input type="checkbox"/> Emergency Department (ED) Arrival Time	<input type="checkbox"/> FOM: Expression
<input type="checkbox"/> ED Arrival Date*	<input type="checkbox"/> Diagnosis ICD-9 Code
<input type="checkbox"/> Hospital Arrival Time	<input type="checkbox"/> Abbreviated Injury Scale (AIS) Code
<input type="checkbox"/> Hospital Arrival Date*	<input type="checkbox"/> Abbreviated Injury Scale (AIS) Severity Score
<input type="checkbox"/> Trauma Type	<input type="checkbox"/> AIS Body Region
<input type="checkbox"/> Trauma Alert Called	<input type="checkbox"/> Injury Severity Score (ISS)
<input type="checkbox"/> Admitting Service	<input type="checkbox"/> Procedure Codes
<input type="checkbox"/> First Pulse Rate at Hospital	<input type="checkbox"/> Procedure ICD-9
<input type="checkbox"/> First Respiratory Rate at Hospital	<input type="checkbox"/> Procedure Location
<input type="checkbox"/> First Temperature at Hospital	<input type="checkbox"/> Procedure Results
<input type="checkbox"/> First Systolic Blood Pressure at Hospital	<input type="checkbox"/> Procedure Start Date*
	<input type="checkbox"/> Procedure Start Time

* Denotes an indirect identifier that may be released.



Central Ohio
Trauma System

CEO/COO DATA RELEASE FORM FOR HOSPITAL-SPECIFIC DATA

TO: _____, Hospital CEO / COO
C: _____, (COTS Board Member)

HOSPITAL:

FROM: Nancie Bechtel, RN, Executive Director

DATE:

REQUESTOR:

REQUEST MODE:

DATA REQUEST:

REQUEST DATES:

I agree to the following:

_____ YES, release the data as requested to the requestor

_____ Release the data but send it only to me

_____ NO, do not release the data

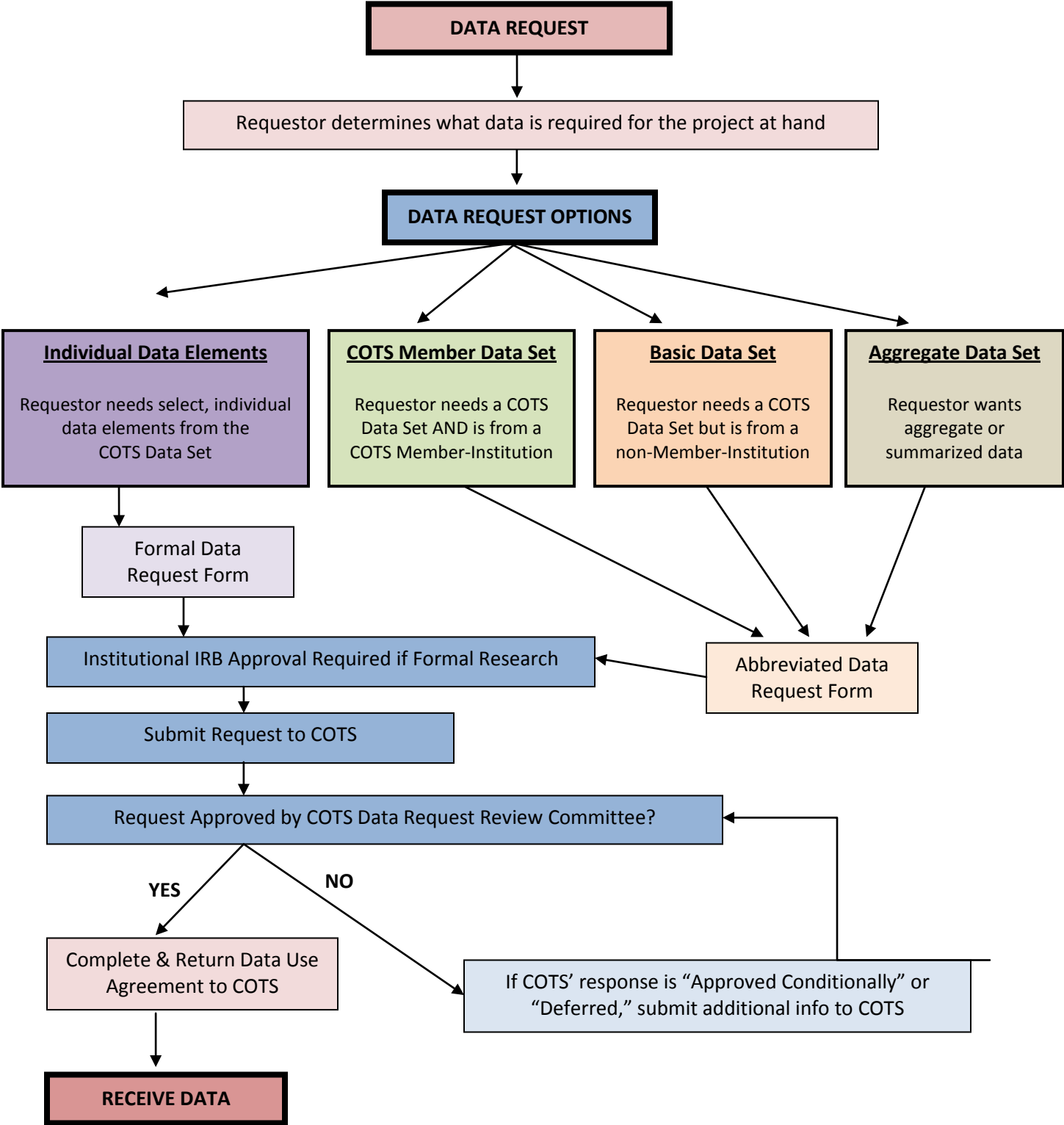
_____ Release the data with the following stipulations: _____

CEO/COO/President Signature

Date

**CENTRAL OHIO TRAUMA SYSTEM (COTS)
DATA REQUEST ALGORITHM**

The following algorithm depicts data request processes of the COTS Regional Registry.



Central Ohio Trauma System

DATA USE AGREEMENT

This Data Use Agreement (the "Agreement") is effective as of _____ 20__ (the "Effective Date") by and between Central Ohio Trauma System ("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 48 hours 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.

DATA USER:

CENTRAL OHIO TRAUMA SYSTEM (COTS)

Signature

Signature

Print Name: _____

Date: _____

Date: _____

Attachment:

Exhibit A: Research Request

EXHIBIT A
RESEARCH REQUEST

[Attach Data User's Research Request here]