



I. INFORMATION FOR DATA USE AGREEMENT: Florida Trauma Registry

Protected Health Information submitted in any format to the Department of Health (Department) Florida Trauma Registry by verified and provisional trauma centers and emergency medical services providers as part of the statewide trauma care system is confidential and exempt from release as a public record pursuant to sections 395.4025(13) and 401.30(4), Florida Statutes. Each year the American College of Surgeons publishes the National Trauma Data Standards to define the data elements to be collected by trauma centers for reporting to the National Trauma Data Bank either directly or via a state trauma registry. A dictionary of the current data elements can be found at: <https://www.facs.org/quality-programs/trauma/tqp/center-programs/ntdb/ntds/data-dictionary>.

[. In Florida, reporting entities submit this data to the Florida Trauma Registry as required by section 395.404, Florida Statutes.](#)

Applicants should review these data elements carefully when requesting data from the Florida Trauma Registry, as the use of each data element must be justified in this application. Florida Trauma Registry data will not be released unless this application demonstrates a need to use the specific data requested in the course of a study described herein that is designed to advance medical research or medical education for the purpose of reducing morbidity or mortality, as required by Chapter 405, Florida Statutes.

Applications to enter into a Data Use Agreement (DUA) are not automatically approved. The Department Institutional Review Board (IRB) has final approval authority for all applications to enter into a DUA to receive data from the Florida Trauma Registry.

Send completed application to:

Trauma Section  
Bureau of Emergency Medical Oversight Florida  
4052 Bald Cypress Way, Bin A-22  
Tallahassee, FL 32399-1722  
Phone: (800) 224-4440  
Fax: (850) 488-2512  
E-mail: [trauma.registry@flhealth.gov](mailto:trauma.registry@flhealth.gov)

<p><b>FOR DOH BEMO USE:</b></p> <p>Date Received: _____</p> <p>Status:</p> <p><input type="checkbox"/> Passes initial review, refer to DOH IRB</p> <p><input type="checkbox"/> Does not pass initial review</p> <p>Trauma Reviewer: _____</p> <p>Comments: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>
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**II. PROJECT SUMMARY.**

A. Title of study or project.
B. List names of organizations, consultants, subcontractors, or any other external collaborators involved with this study or project, other than the project director and his or her staff.
C. List all sources of funding for this study or project.
D. In the space below or on a separate sheet, please provide a summary of the study protocol or project activities that addresses each of the items below. You may also attach a copy of your proposed study or project protocol, or any other supporting documentation. Note: All items below must be addressed in this summary. <ul style="list-style-type: none"><li>• Demonstrate how this study or project will reduce morbidity and mortality;</li><li>• A description of the analysis to be conducted using the Florida Trauma Registry data, including the specific health or medical conditions to be examined, and specific testable hypotheses, if any;</li><li>• A listing of all other data sources to be used in this study or project, and any proposed linkages to these data sources;</li><li>• A timetable for completion of this study or project; and</li><li>• A description of how, when, and to whom research results will be released, including publication or presentation of findings, and how results will advance medical research and medical education for the purpose of reducing morbidity or mortality. Please describe the least aggregate results to be released. Attach examples to demonstrate that the information will be properly aggregated and de-identified.</li></ul>





## V. DATA USE

Florida Trauma Registry data may only be used for the specific purpose(s) described in this agreement. All persons with data access must maintain the confidentiality of the data and prevent release to unauthorized parties. The applicant agrees as follows:

1. The applicant will not, nor permit others to, attempt to link records with personally identifiable records from any other source, with the purpose of identifying an individual patient or other entities unless otherwise approved by the Department;
2. The applicant will not, nor permit others to, release any information that identifies individuals, directly or indirectly;
3. The applicant will not, nor permit others to, use the data for any study of human subjects that was not specifically approved by the IRB;
4. The applicant will not, nor permit others to, make statements indicating or suggesting that interpretations drawn from the data are those of the Department;
5. The applicant will indemnify, defend, and hold the Department, its members, employees, and contract vendors, harmless from any and all claims and losses accruing to any person as a result of violation of this DUA;
6. The applicant will not, nor permit others to, copy, sell, rent, license, lease, loan, or otherwise grant access to the data covered by this DUA to any other person or entity;
7. The applicant will not, nor permit others to, release individual records, either in part or in their entirety, to any person who is not a member of the research or study group identified in this DUA;
8. The applicant will not, nor permit others to, make follow-back of any type to any individual, institution, or firm without the prior knowledge and express approval of the IRB;
9. The applicant will delete the data according to one of the approved data destruction methods indicated in this DUA;
10. The applicant may be audited by the Department Bureau of Emergency Medical Oversight at any time to ensure that the data are being used as approved and deleted upon conclusion of the approved study or project;
11. The applicant will abide by, in addition to this DUA, all terms and conditions established by the Department, the IRB, the Bureau of Emergency Medical Oversight, and, if applicable, the applicant's own organizational institutional review board, governing boards, bodies, and entities; and is solely responsible for the timely submission of all review application materials and the payment of all applicable review fees; and
12. The applicant will furnish a copy of the results of the study to the Bureau of Emergency Medical Oversight within 60 days of the completion of the study or project.

## VI. DATA DESTRUCTION METHOD

Applicants must make provisions for the destruction of data at the conclusion of their project, or when the data is no longer required. Maintaining the privacy of the individuals whose protected health information is included in Florida Trauma Registry data is essential to preserving the integrity of the data sharing process.

***Please detail the manner and timeline for destruction. If you are following a data destruction policy set by your organization or agency, please attach that policy to your application.***



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**VII. SIGNATURE OF PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR.**

By signing below, I understand that upon Department approval of this DUA, I must submit a separate online application to the IRB. I understand that the IRB must review and approve my proposed study or project, that I must pay the applicable review fee, and that I may not share Florida Trauma Registry data externally or internally with unauthorized persons. I agree to use the data only for the purpose stated in this application. I agree to secure the data and any reports containing the data, and to securely dispose of the data and reports, so that confidentiality will not be breached. I acknowledge that it is my responsibility to obtain review and approval of my proposed study or project from my own organizational institutional review board, governing boards, bodies, and entities, as requires thereby.

\*\*\* All persons who come in direct contact with the Florida Trauma Registry data requested in this application must sign the DUA. Provide all required additional signatures on the last page of this application.

Project Director/Principal Investigator (Print Full Name)

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Project Director/Principal Investigator(Signature) \_\_\_\_\_ Date Signed \_\_\_\_\_

STATE OF FLORIDA  
COUNTY OF:

The foregoing instrument was acknowledged before me by means of  physical presence or  online notarization, this day of \_\_\_\_\_, (year) \_\_\_\_\_, by \_\_\_\_\_ (name of person acknowledging) .

\_\_\_\_\_  
(Signature of Notary Public - State of Florida)  
\_\_\_\_\_  
(Print, Type, or Stamp Commissioned Name of Notary Public)

Personally Known OR Produced Identification  
Type of Identification Produced

Primary Custodian (Print Full Name)

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Primary Custodian (Signature) \_\_\_\_\_ Date Signed \_\_\_\_\_

STATE OF FLORIDA  
COUNTY OF

The foregoing instrument was acknowledged before me by means of  physical presence or  online notarization, this day of \_\_\_\_\_, (year) \_\_\_\_\_, by \_\_\_\_\_ (name of person acknowledging) .

\_\_\_\_\_  
(Signature of Notary Public - State of Florida)  
\_\_\_\_\_  
(Print, Type, or Stamp Commissioned Name of Notary Public)

Personally Known OR Produced Identification  
Type of Identification Produced:



Corporate Applicant as Project Director/Primary Investigator:

\_\_\_\_\_  
(Print Full Name of Corporate Representative)

Corporate Applicant Representative (Signature)\_\_\_\_\_ Date Signed \_\_\_\_\_

STATE OF FLORIDA  
COUNTY OF

The foregoing instrument was acknowledged before me by means of  physical presence or  online notarization, this day of \_\_\_\_\_, (year) \_\_\_\_\_, by (name of person) as (type of authority, . . . . e.g. officer, trustee, attorney in fact) for (name of party on behalf of whom instrument was executed) .

\_\_\_\_\_  
(Signature of Notary Public - State of Florida)

\_\_\_\_\_  
(Print, Type, or Stamp Commissioned Name of Notary Public)

Personally Known OR Produced Identification  
Type of Identification Produced

Corporate Applicant as Data Custodian (Print Full Name of Corporate Representative)

Corporate Applicant Representative (Signature)\_\_\_\_\_ Date Signed \_\_\_\_\_

STATE OF FLORIDA  
COUNTY OF:

The foregoing instrument was acknowledged before me by means of  physical presence or  online notarization, this day of \_\_\_\_\_, (year) \_\_\_\_\_, by (name of person) as (type of authority, . . . . e.g. officer, trustee, attorney in fact) for (name of party on behalf of whom instrument was executed) .

\_\_\_\_\_  
(Signature of Notary Public - State of Florida)

\_\_\_\_\_  
(Print, Type, or Stamp Commissioned Name of Notary Public)

Personally Known OR Produced Identification  
Type of Identification Produced:





**FOR OFFICE USE ONLY:**

\_\_\_\_\_  
Signature of BEMO Bureau Chief

\_\_\_\_\_  
Date

Signatures below are by individuals who will access the data requested in this DUA and acknowledge and accept all terms herein.

Name: \_\_\_\_\_  
(Please Print)  
Signature: \_\_\_\_\_

Name: \_\_\_\_\_  
(Please Print)  
Signature: \_\_\_\_\_

Name: \_\_\_\_\_  
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Signature: \_\_\_\_\_