FLORIDA DEPARTMENT OF HEALTH
Division of Emergency Preparedness and Community Support
Bureau of Emergency Medical Oversight

Bureau of Emergency Medical Oversight Data Use Agreement

I. INFORMATION FOR DATA USE AGREEMENT

Health care records submitted to the department from licensed EMS providers are made confidential and exempt from public records requests by section 401.30(4), Florida Statutes. The Department has created an electronic means by which the licensee can transfer individual patient care records of emergency calls to the department called the Emergency Medical Services Tracking and Reporting System (EMSTARS). A list of data elements available is can be found at www.floridaemstars.com . Certain data elements are confidential, as they could be used to identify individuals. Applicants should review these data elements carefully when requesting data, as the use of each data element must be justified in this application. ***Please note that data may not be released unless there is a documented need demonstrating the advancement of medical research or medical education in the interest of reducing morbidity or mortality pursuant to Chapter 405 Florida Statutes.***

Application approvals for the use of prehospital data are not granted automatically, but are reviewed by the department based upon their potential to reduce morbidity and mortality and advance medical research and medical education. Review and approval by the Florida Department of Health, Institutional Review Board (IRB) is required for all data that is released.

Send completed application to:

Health Information and Policy Analysis Section
Bureau of Emergency Medical Oversight
Florida Department of Health
4052 Bald Cypress Way, Bin A-22
Tallahassee, FL 32399-1722
Phone: (800) 224-4440
Fax: (850) 488-2512
E-mail: ZZZemstars@doh.state.fl.us

FOR DOH BEMO USE:

Date Received_____

Status:

☐ Passes initial review, refer to DOH IRB
☐ Does not pass initial review

Request #:_____

Comments:_____

_____

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II. APPLICANT INFORMATION.

A. Project Director/ Principal Investigator:	
Title:	
Organization:	
Address:	
Phone:	
Fax:	
E-mail:	
B. Data Custodian (to whom the data should be released):	
Title:	
Organization:	
Address:	
Phone:	
Fax:	
E-mail:	

Please attach a curriculum vitae for each individual listed above and for each co-investigator.*

C. Provide the names and titles of all proposed data release agreement signatories.

Please indicate the study group(s) below that best describe(s) the applicant			
☐	Research groups (universities)	☐	Medical associations and societies
☐	In-hospital medical staff committees	☐	Other Governmental health agencies
☐	Other Agency not listed: (Please Explain)		
Tax Status: ☐ Not-For-Profit ☐ For-Profit			

III. 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, in addition to this summary. **Note:** All items below *must* be addressed in this summary. • Demonstrate how this study or project will reduce morbidity and mortality; • A description of the analysis to be conducted **using Florida prehospital data**, including the specific health or medical conditions to be examined, and specific testable hypotheses, if any; • A listing of all other data sources to be used in this study or project, and any proposed linkages to these data sources; • A timetable for completion of this study or project; and • 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. Please describe the *least* aggregate results to be released. Attach examples as needed to demonstrate that the information will be properly aggregated and/or de-identified.

IV. REQUESTED DATA SPECIFICATIONS AND REQUIREMENTS.

The collection of electronic incident level data collection began in July 2007 from voluntarily participating EMS agencies. The collection of prehospital data is in accordance with "The Florida EMS Data Dictionary 1.4 and 3.0 that can be found at www.floridaemstars.com .

A. Date Range Requested :				
B. Data Selection/Extraction Criteria				
☐	None (you will receive all unrestricted data within the EMSTARS database)			
☐	Specific patient population			
Identify specific patient population requested in the space below (e.g. age > 65, specific ICD-9-CM codes), if applicable.				
C. Data Format Requested				
☐	SAS	☐ Excel	☐ XML	
☐	Other-Not Listed			

V. DATA USE

Prehospital 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 EMS agency 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 Florida Department of Health Institutional Review Board;
4. The applicant will not, nor permit others to, make statements indicating or suggesting that interpretations drawn from the data are those of the Florida Department of Health;
5. The applicant will indemnify, defend, and hold the Florida Department of Health, 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 agreement;

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 agreement 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 agreement;
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 approval of the Florida Department of Health Institutional Review Board;
9. The applicant will delete the data according to one of the approved data destruction methods indicated in this agreement;
10. The applicant may be audited by the BEMO 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 data use agreement, all terms and conditions of the Florida Department of Health Institutional Review Board, BEMO, and, if applicable, the applicant's own organizational Institutional Review Board, 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 BEMO within 60 days of the completion of the study or project.

VI. DATA DESTRUCTION METHOD

Applicants must make provisions for the destruction of records at the conclusion of their project, or when the data is no longer required. Maintaining the privacy of the individuals whose personal information is included in prehospital 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.

VII. SIGNATURE OF PROJECT DIRECTOR/PRINCIPAL INVESTIGATOR.

By signing below, I understand that upon passing initial review of this data use agreement, I agree to submit a separate online application to the Florida Department of Health, Institutional Review Board (DOH IRB), for review and approval of my proposed study or project. I understand that the DOH IRB must review and approve my proposed study or project, that I must pay the applicable review fee, and that not to share the data externally or internally with unauthorized persons. I agree to use the data only for the purpose stated in this form. I agree to secure the data and any reports containing the data, including disposition of the data and reports, so that confidentiality will not be breached. I acknowledge that it is my responsibility to obtain IRB review and approval of my proposed study or project from my own institution, if my institution does not defer to the authority of the Department of Health's accredited IRB.

****** All persons who come in direct contact with the data requested in this form are required to sign this agreement. If additional signatures are required, please provide them on the last page of this agreement.***

Principle Investigator's or Primary Custodian's Name (Please Print)

_____

Principle Investigator's or Primary Custodian's Signature (Notarization Required)

_____

Attest (If applicant is a corporation):_____
(As Corporate Secretary)

Subscribed and sworn before me _____ this _____day of_____, 20_____

Notary Public, State of _____
Notary Public Signature (Affix Notary Stamp)

FOR OFFICE USE ONLY

_____
Signature of BEMO Bureau Chief ***Date***

_____
Signature of Division Director ***Date***

Signatures below, by individuals who will access the data requested in this agreement, acknowledge agreement to the terms of the Data Use Agreement.

Name: _____
(Please Print)
Signature: _____

Name: _____
(Please Print)
Signature: _____

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