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.

Records of emergency medical services calls (EMS Records) are confidential and exempt from release as public records pursuant to sections 395.4025(13) and 401.30(4), Florida Statutes. The majority of emergency medical services providers submit EMS Records to the Department by the electronic transmission of data elements (see www.floridaemstars.com) into the Emergency Medical Services Tracking and Reporting System (EMSTARS).

Chapter 405, Florida Statutes, prohibits the release of EMS Records submitted via EMSTARS (Data) unless the applicant for release describes herein a study or project that is designed to advance medical research or medical education for the purpose of reducing morbidity or mortality and justifies the use of the Data in such study or project.

The Department will conduct an initial review of this application. Passage of the initial review **is not** a grant of approval to obtain Data. The Department Institutional Review Board (IRB) has final approval authority of all applications. If this application is approved by the IRB and executed in accordance with the law and the terms herein, this application and any attachments will form the entire Data Use Agreement (DUA) between the parties.

II. APPLICANT INFORMATION.

Send completed application to: Bureau of Emergency Medical Oversight Florida Department of Health 4052 Bald Cypress Way, Bin A-22 Tallahassee, FL 32399-1722 Phone: (850) 224-4440 Fax: (850) 488-2512 E-mail: EMSTARS@flhealth.gov	**FOR DEPARTMENT USE:** Date Received: _____ Status: ☐ Passes initial review, refer to Department's IRB ☐ Does not pass initial review Request #:_____ Comments:_____ _____ _____ _____ _____

A. Project Director or Principal Investigator:	
Title:	
Organization:	
Address:	
Phone:	
Fax:	
E-mail:	
B. Data Custodian (individual responsible for receipt of Data):	
Title:	
Organization:	
Address:	
Phone:	
Fax:	
E-mail:	

Attach a curriculum vitae for each individual listed above and for any co-investigators.

C. Name and title of each proposed party (signatory) to this DUA:	

D. Applicant entity type:

☐	University research group	☐	Medical association or society
☐	In-hospital medical staff committee	☐	Governmental health agency
☐	Other agency or entity not listed above:		

E. Tax Status: ☐ Not-For-Profit ☐ For-Profit

III. STUDY OR PROJECT SUMMARY.

A. Study or project title:	
B. External collaborators not named herein, e.g., governmental entities, organizations, consultants, subcontractors, and vendors:	
C. All sources of direct, indirect, public, and private funding for the study or project:	
D. In the space provided or on a separate sheet, summarize the study protocol or project activities that address each item below. Copies of the proposed study, project protocol, or other supporting documentation may be provided **in addition to** the required summary; HOWEVER, the summary itself must include each item below.	
a) A demonstration of how the study or project will reduce morbidity and mortality.	
b) A description of the analysis to be conducted using the Data, including the specific health or medical conditions to be examined, and specific testable hypotheses, if any.	
c) A listing of all other data sources to be used and any proposed linkages to the other data sources.	
e) 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.	
E. Describe the least aggregate results to be released. Attach examples showing how the Data will be properly aggregated and de-identified:	

IV. REQUESTED DATA SPECIFICATIONS AND REQUIREMENTS.

Indicate the requested date ranges and data types below. Data is available from as early as July 2007. Please note, however, that emergency medical services providers are not statutorily required to submit EMS Records via EMSTARS.

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

V. DATA USE.

Data may only be used for the specific purpose(s) described in this application and approved in the DUA. All persons with Data access are liable for maintaining the confidentiality of the Data and preventing release to unauthorized parties. The applicant agrees as follows:

A. The applicant will not, nor permit others to, attempt to link Data with personally identifiable data from any other source with the intent to identify an individual or an emergency medical services provider unless prior written approval is granted by the IRB.
B. The applicant will not, nor permit others to, release any information that identifies individuals, directly or indirectly.
C. The applicant will not, nor permit others to, use the Data for any study or project that is not expressly approved in an executed DUA.
D. The applicant will not, nor permit others to, make statements indicating or suggesting that interpretations drawn from the Data are those of the Department or the IRB.
E. **The applicant will indemnify, defend, and hold the Department, the IRB, and their 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 or use of the Data in a manner not approved by this DUA**.
F. The applicant will not, nor permit others to, copy, sell, rent, license, lease, loan, or otherwise grant access to the Data to any person or entity not a party to this DUA or identified in this application.
G. The applicant will not, nor permit others to, release individual records or Data, either in part or in their entirety, to any person who is not an identified in this DUA or a member of

the research or study group (e.g., research assistant, student, employee) identified in this agreement.

H. The applicant will not, nor permit others to, make follow-back or other attempted contact of any type with any individual, institution, firm, or entity unless prior written approval is granted by the IRB.
I. The applicant will delete the Data using one of the approved data destruction methods indicated in this DUA.
J. The applicant will cooperate and assist the Department in a compliance audit of applicants at any time during the study or project and after the conclusion of the study or project.
K. The applicant will abide by this DUA, any terms and conditions required by the IRB in a writing incorporated into this DUA, and any written approval of the IRB as authorized above.
L. The applicant will abide by any applicable requirements established by the applicant's own organizational IRB.
M. The applicant is solely responsible for the timely submission of this application, supporting documentation, and applicable fees.
N. The applicant will furnish a copy of the results of the study or project to the Department within 60 days of the completion of the study or project.

VI. DATA DESTRUCTION METHOD.

Data sharing will only be permitted so long as applicants destroy Data after the conclusion of the study or project, or when the Data is no longer required for the study or project.

Describe, in detail, the manner and timeline for Data destruction. If using a data destruction policy and procedure established by the applicant's institution, organization, agency, etc., attach a copy of the policy and procedure to this application and provide the name and contact information of the individual at the applicant's institution, organization, agency, etc., who is available and authorized to verify the policy and procedure.

VII. SIGNATURE OF STUDY OR PROJECT DIRECTOR OR PRINCIPAL INVESTIGATOR.

By signing below, I understand and agree that upon initial approval of this Data Use Agreement, I will submit a separate online application to the Department's Institutional Review Board for review and approval. I understand that the IRB must approve the proposed study or project, that I must pay the applicable review fee, and that I will not distribute the Data externally or internally with unauthorized persons. I will use the Data only for the purpose stated in the approved and executed DUA. I will secure the Data and any reports, documents, electronic storage devices, and any other device containing the Data, including documentation and records of the disposition of the Data, so that confidentiality will not be breached. I acknowledge that it is my responsibility to obtain review and approval of the proposed study or project from the institution, organization, or entity where I am employed or will originate the study or project, and any institutional review board thereof if my institution does not defer to the authority of the Department's IRB.

****** All persons who will have direct contact with or access to the Data must sign this agreement. Reproduce this page and attach for each individual required to sign.***

_____

Principal Investigator or Primary Custodian
(Print Name)

_____ _____

Principal Investigator or Primary Custodian ***Date***
(Signature)

_____

Investigator or Custodian
(Print Name)

_____ _____

Investigator or Custodian ***Date***
(Signature)

FOR OFFICE USE ONLY

_____

Chief, Bureau of Emergency Medical Oversight, Department of Health ***Date***

_____

Director, Division of Emergency Preparedness and Community Support ***Date***