FIELD RESEARCH: PREHOSPITAL EMERGENCY CARE

I. AUTHORITY:

Title 22, Section 1797.221: "The medical director of the local EMS agency may approve or conduct any scientific or trial study of the efficacy of the prehospital emergency use of any drug, device, or treatment procedure within the local EMS system, utilizing any level of prehospital emergency medical care personnel. The study shall be consistent with any requirements established by the authority for scientific or trial studies conducted within the prehospital emergency medical system, and, where applicable, with Article 5 (commencing with Section 111550) of Chapter 6of Part 5 of Division 104). No drug, device, or treatment procedure which has been specifically excluded by the authority from usage in the EMS system shall be included in such a study.

II. APPLICATION:

This policy defines the process for application and approval to conduct research relating to prehospital care.

III. DEFINITIONS:

"Research"- means any investigation which may alter - prehospital patient care procedures which are currently defined by the State Law and Rules and Regulations.

IV. CRITERIA:

A. An individual(s) or organization(s) proposing to conduct research shall submit the following information in writing to the Orange County Emergency Medical Services (OCEMS) Medical Director:

1. An outline including the following:

   a. A description of the additional procedure(s) or drug(s) proposed and the medical conditions for which they can be utilized.

   b. A description of a proposed study design including the scope of the study, method of evaluating the effectiveness of the additional procedure(s) or drug(s), and a review of the relevant medical literature.

   c. Policies and procedures to be instituted by the OCEMS regarding the use and medical control of the additional procedure(s) or drug(s).

   d. A description of the additional training and competency testing required to implement these changes.

   e. Evaluation requirements and techniques.

   f. Time frames.

   g. Medicolegal implications, if any, including copies of applicable legal consultations.

   h. Protection of patient safety and quality monitoring

   i. Federal Drug Administration (FDA) approval of drug and/or equipment, if applicable.

2. Evidence of consideration for a patient's right of privacy and confidentiality of medical records as deemed necessary.

3. Copy of notice(s) to all hospitals, appropriate political jurisdictions involved or affected by the research, and other entities as appropriate, of the purpose and intent of the research.

4. Approval from the appropriate base hospital official and appropriate hospital committee(s) (or other entities) involved in the research as deemed necessary.

5. Approval of the appropriate fire chief(s) of the service areas involved.

B. All such research shall be subject to all constraints which apply to research involving humans (Health and Safety Code, Chapter 1.3, Sections 24170 - 24179.5)

C. All such research shall be conducted with the knowledge and concurrence of the Base Hospital(s) (BH) involved.

D. The OCEMS shall submit the proposal with its recommendations to the Paramedic Advisory Subcommittee of the Emergency Medical Care Committee for review and comment.

E. Upon approval by the OCEMS Medical Director, the individual(s) or organization conducting the research shall:

1. Notify all hospitals and appropriate political jurisdictions involved or affected by the research of the OCEMS Medical Director's approval of the research.

2. Conduct training sessions for all agencies and personnel involved in the research, if necessary.

3. Submit a final report to the Paramedic Advisory Subcommittee and the OCEMS Medical director. Interim or status reports shall be submitted as requested by the OCEMS Medical Director.

4. Notify OCEMS Medical Director in case of any change in service medical director, FD Chief, etc. to show continued support of the Research.

V. EMS AUTHORITY REVIEW:

A. Commission on EMS shall review the above report within two (2) meetings and advise the EMS Authority to do one of the following:

1. Terminate the study if there are adverse effects or no benefit from the study is shown;

2. Continue the study for a maximum of eighteen (18) additional months if possible but inconclusive benefit is shown; or

3. Initiate regulatory process if definite benefit is shown. The study may continue while this process takes place.

B. If option (A)(2) is selected, the Commission on EMS may recommend continuation of the study as structured or alteration of the study to increase the validity of the results

C. At the end of the additional eighteen (18) month period mandated in (A)(2), a final report shall be submitted by the OCEMS medical director.

D. The Commission on EMS shall review the final report and advise the EMS Authority to do one of the following:

1. Terminate the study; or

2. Initiate the regulatory process to include the procedure in the mandatory or optional Paramedic scope of practice. (The study may continue while this process takes place.)

E. Any action taken by the EMS Authority after receiving advice from the Commission on EMS reached under (A) or (B) above shall be binding on the local EMSA.

Approved:

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OCEMS Medical Director

Tammi McConnell, MSN, RN
OCEMS Administrator

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